**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

**FORM 10-K**

**☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2021

**☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 001-38803

**HOTH THERAPEUTICS, INC.**
(Exact name of registrant as specified in charter)

| **Nevada** | **82-1553794** |
|---|---|
| (State or jurisdiction of Incorporation or organization) | I.R.S. Employer Identification No. |
| **1 Rockefeller Plaza, Suite 1039, New York, New York** | **10020** |
| (Address of principal executive offices) | (Zip code) |

**(646) 756-2997**
(Registrant's telephone number, including area code)

**Securities registered pursuant to Section 12(b) of the Act:**

| Title of Each Class | Trading Symbol(s) | Name of Each Exchange on Which Registered |
|---|---|---|
| **Common Stock, par value $0.0001 per share** | **HOTH** | **The Nasdaq Stock Market LLC** |

**Securities registered pursuant to Section 12(g) of the Act: None.**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ | Smaller Reporting Company | ☒ |
| | | Emerging Growth Company | ☒ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act) Yes ☐ No ☒

The aggregate market value of the voting stock and non-voting common equity held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter ended June 30, 2021 was $36,736,875 based upon the closing price of the registrant's common stock of $1.60 on The Nasdaq Capital Market as of that date.

Number of shares of common stock outstanding as of March 28, 2022 was 23,975,098.

Documents Incorporated by Reference: None.

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## CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Any statements in this Annual Report on Form 10-K about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. These statements are often, but not always, made through the use of words or phrases such as "believe," "will," "expect," "anticipate," "estimate," "intend," "plan" and "would." For example, statements concerning financial condition, possible or assumed future results of operations, growth opportunities, industry ranking, plans and objectives of management, markets for our common stock and future management and organizational structure are all forward-looking statements. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, levels of activity, performance or achievements expressed or implied by any forward-looking statement.

Any forward-looking statements are qualified in their entirety by reference to the risk factors discussed throughout this Annual Report on Form 10-K. Some of the risks, uncertainties and assumptions that could cause actual results to differ materially from estimates or projections contained in the forward-looking statements include, but are not limited to:

- our business strategies;
- the timing of regulatory submissions;
- our ability to obtain and maintain regulatory approval of our existing product candidates and any other product candidates we may develop, and the labeling under any approval we may obtain;
- risks relating to the timing and costs of clinical trials and the timing and costs of other expenses;
- risks related to market acceptance of products;
- intellectual property risks;
- risks associated to our reliance on third party organizations;
- our competitive position;
- our industry environment;
- our anticipated financial and operating results, including anticipated sources of revenues;
- assumptions regarding the size of the available market, benefits of our products, product pricing and timing of product launches;
- management's expectation with respect to future acquisitions;
- statements regarding our goals, intentions, plans and expectations, including the introduction of new products and markets; and
- our cash needs and financing plans.

The foregoing list sets forth some, but not all, of the factors that could affect our ability to achieve results described in any forward-looking statements. You should read this Annual Report on Form 10-K and the documents that we reference herein and have filed as exhibits to the Annual Report on Form 10-K, completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this Annual Report on Form 10-K is accurate as of the date hereof. Because the risk factors referred to on page 13 of Annual Report on Form 10-K, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and except as required by law, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of the information presented in this Annual Report on Form 10-K, and particularly our forward-looking statements, by these cautionary statements.

## RISK FACTOR SUMMARY

Our business is subject to significant risks and uncertainties that make an investment in us speculative and risky. Below we summarize what we believe are the principal risk factors but these risks are not the only ones we face, and you should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors," together with the other information in this Annual Report on Form 10-K. If any of the following risks actually occurs (or if any of those listed elsewhere in this Annual Report on Form 10-K occur), our business, reputation, financial condition, results of operations, revenue, and future prospects could be seriously harmed. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business.

**Risk Related to our Financial Position and Need for Capital**

- We have generated no revenue from commercial sales and our future profitability is uncertain. If we fail to obtain the capital necessary to fund our operations, we will be unable to continue or complete our product development.

**Risk Related to Product Development, Regulatory Approval, Manufacturing and Commercialization**

- The marketing approval process is lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for the product candidates we intend to develop, our business may be substantially harmed.

- We may encounter substantial delays in completing our clinical studies which in turn will require additional costs, or we may fail to demonstrate adequate safety and efficacy to the satisfaction of applicable regulatory authorities. If we are not able to obtain any required regulatory approvals for our product candidates, we will not be able to commercialize our product candidates and our ability to generate revenue will be limited.

- Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.

- We rely on and intend to rely on third parties to conduct our clinical trials, to assist us with pre-clinical development and for manufacturing and marketing of our proposed product candidates. If we are not able to secure favorable arrangements with such third parties, or such third parties do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products and our business and financial condition could be harmed.

- Even if our product candidates are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing U.S. Food and Drug Administration regulations or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

- Our revenue stream will depend upon third-party reimbursement.

- Our products will face significant competition, and if they are unable to compete successfully, our business will suffer.

- If we fail to comply with healthcare regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected.

**Risk Related to our Intellectual Property Rights**

- Our business depends upon us securing and protecting critical intellectual property.
- We rely upon licenses granted to us by various licensors, and if such licensors do not adequately defend such licenses, our business may be harmed.
- Patent positions in our industry are highly uncertain and involve complex legal and factual questions.

**Risk Related to our Company**

- We have expanded and may continue to expand, our business through the acquisition of rights to new drug candidates that could disrupt our business, harm our financial condition and may also dilute current shareholders' ownership interests in our Company.
- If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business.
- Any international operations we undertake may subject us to risks inherent with operations outside of the United States.
- Our Amended and Restated Bylaws provide that the Eighth Judicial District Court of Clark County, Nevada will be the sole and exclusive forum for certain disputes which could limit shareholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

**General Risk Factors**

- Market and economic conditions may negatively impact our business, financial condition and share price.
- Future sales and issuances of our securities could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to fall.
- We do not intend to pay cash dividends on our shares of common stock so any returns will be limited to the value of our shares.
- If we are unable to maintain listing of our securities on The Nasdaq Capital Market or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired.

## PART I

Throughout this Annual Report on Form 10-K, the "Company," "Hoth," "we," "us," and "our" refers to Hoth Therapeutics, Inc., individually, or as the context requires, collectively with its subsidiary, Hoth Therapeutics Australia Pty Ltd.

### ITEM 1. BUSINESS

#### Overview

We are a clinical-stage biopharmaceutical company focused on developing new generation therapies for unmet medical needs. We are focused on developing (i) a topical formulation for treating side effects from drugs used for the treatment of cancer; (ii) a treatment for mast-cell derived cancers and anaphylaxis; and (iii) a treatment and/or prevention for Alzheimer's or other neuroinflammatory diseases. We also have preclinical assets being developed for (i) atopic dermatitis (also known as eczema); (ii) a treatment for asthma and allergies using inhalational administration; (iii) a treatment for lung diseases resulting from bacterial infections; and (iv) a treatment for inflammatory bowel diseases. We are also developing a diagnostic device via a mobile device.

#### Primary Development:

***HT-001***

On February 1, 2020, we entered into a patent license agreement with The George Washington University ("GW") pursuant to which GW granted us a license to certain patent rights to, among other things, make, use, offer and sell certain licensed products throughout the world with respect to HT-001 which we intend to potentially use for treating dermatological side effects from epidermal growth factor receptor ("EGFR") inhibitors, and potentially other drugs used for the treatment of cancer. HT-001 is a topical formulation under development for the treatment of patients with rash and skin disorders associated with initial and repeat courses of tyrosine kinase EGFR inhibitor therapy. EGFR inhibitors are used for the treatment of cancers with EGFR up-regulation (such as non-small cell lung cancer, pancreatic cancer, breast cancer and colon cancer); however, EGFR inhibitors are often associated with dose-limiting skin toxicities that can result in the interruption or reduction of treatment. HT-001 is targeted to treat these EGFR-induced skin disorders to allow patients to achieve the best potential outcomes of EGFR therapy. HT-001 has achieved positive results in its initial pre-clinical studies conducted at GW. In December 2020, we submitted a pre-IND meeting request to the FDA with respect to HT-001 as a concomitant therapy with EGFR inhibitors. In preparation for such pre-IND meeting, we prepared and submitted to the FDA our IND-opening clinical trial plan in January 2021, which includes two phase 2 trials conducted in patients. Based on the FDA's feedback, we intend to advance our IND-enabling activities for HT-001 as planned. We have engaged Worldwide Clinical Trials ("Worldwide") as our clinical research organization to provide clinical management, data management, biostatistical, medical monitoring, pharmacovigilance, and other related services to support the CLEER1 Phase 2a clinical trial in the United States.

We believe that the key elements for our market success with respect to HT-001 include:

- To our knowledge, there are currently no drugs approved for the treatment of skin toxicities associated with EFGR inhibitor therapy and 49-100% of patients develop skin toxicities during EGFR inhibitory therapy;
- The main active ingredient of HT-001 is already approved in oral and IV dosage forms which supports pursuit of the 505(b)(2) regulatory pathway to reduce development time and cost;
- To our knowledge, there are no current topical formulations available using HT-001's active ingredient so we believe that there is no direct market competition; and
- We have the potential to pursue other indications such as chronic pruritus, atopic dermatitis and other skin toxicities that develop from anti-cancer therapies using the HT-001 formulation.

***HT-KIT***

We have obtained from North Carolina State University an exclusive, worldwide, royalty bearing license to certain intellectual property to, among other things, discover, develop, make, have made, use and sell certain licensed products and sell, use and practice certain licensed services with respect to cancer and anaphylaxis; this is being developed as HT-KIT. The HT-KIT drug is designed to more specifically target the receptor tyrosine kinase KIT in mast cells, which is required for the proliferation, survival and differentiation of bone marrow-derived hematopoietic stem cells. Mutations in the KIT pathway have been associated with several human cancers, such as gastrointestinal stromal tumors and mast cell-derived cancers (mast cell leukemia and mast cell sarcoma). Based on the initial proof-of-concept success, we intend to initially target mast cell neoplasms for development of HT-KIT, which is a rare, aggressive cancer with poor prognosis.

The same target, KIT, also plays a key role in mast cell-mediated anaphylaxis, a serious allergic reaction that is rapid in onset and may cause death. Anaphylaxis typically occurs after exposure to an external allergen that results in an immediate and severe immune response. We also intend to pursue the anaphylaxis indication for HT-KIT in parallel to cancer treatment.

On December 21, 2021, we submitted an Orphan Drug Designation ("ODD") request to the U.S. Food and Drug Administration ("FDA") for HT-KIT for the treatment of mastocytosis, and on March 10, 2022, we received ODD for HT-KIT for the treatment of mastocytosis. Drugs intended to treat orphan diseases (rare diseases that affect less than 200,000 people in the U.S.) are eligible to apply for ODD, which provides benefits such as 7 year marketing exclusivity and tax incentives to the sponsor during development and after approval.

***HT-ALZ***

On February 23, 2021, we filed a provisional patent application with the United States Patent and Trademark Office for the use of the active ingredient of HT-001 to treat and prevent Alzheimer's disease and other neuroinflammatory diseases.

We intend to develop HT-ALZ for use in patients following the Section 505(b)(2) regulatory pathway of the FDA rules. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA") was enacted to enable sponsors to seek New Drug Application ("NDA") approval for novel repurposed drugs without the need for such sponsors to undertake time consuming and expensive pre-clinical safety studies and Phase 1 safety studies. Proceeding under this regulatory pathway, we will be able to rely upon publicly available data with respect to our active ingredient in our NDA submission to the FDA for marketing approval.

On June 7, 2021, we entered into a sponsored research agreement with The Washington University to investigate the effects of HT-ALZ on behavioral and pathological markers of Alzheimer's disease and to determine if HT-ALZ can improve learning and memory in an animal model of Alzheimer's disease. Our study will also determine if behavior is improved utilizing HT-ALZ in blocking NK-1Rs. The study commenced in August 2021 and we expect preclinical results in 2022.

***The BioLexa Platform***

We have obtained an exclusive license from the University of Cincinnati to make, use, have made, import, offer for sale, and sell products based upon or involving the use of (i) topical compositions comprising a zinc chelator and gentamicin and (ii) zinc chelators to inhibit biofilm formation (the "BioLexa Platform" or "BioLexa"). The license enables us to develop the platform for any indications in humans.

The BioLexa Platform is a proprietary, patented, drug compound platform for the treatment of eczema. It combines an FDA approved zinc chelator with one or more approved antibiotics in a topical dosage form to address unchecked eczema flare-ups by preventing the formation of infectious biofilms and the resulting clogging of sweat ducts.

The technology is based on scientific research into the mechanism of Staphylococcus biofilm formation conducted by Andrew B. Herr, PhD at the University of Cincinnati. Dr. Herr conducted multiple in-vitro experiments, or experiments conducted in a controlled environment outside of a living organism, demonstrating that chelation of zinc can prevent Staphylococcus bacteria from forming complex colonies called a biofilm. Biofilms are used by bacteria as a defense mechanism against the host immune response and antibiotics. Prevention of the biofilm formation leaves the bacteria in their planktonic, or single cell state and susceptible to host immune defenses and antibiotic therapy. Dr. Herr's in-vitro work demonstrating that zinc is an enabler for *staph*-biofilm formation led to the design and implementation of a series of in-vivo experiments, or experiments conducted using living organisms. These experiments were conducted at the University of Miami using a minipig wound infection model and intended to demonstrate that the combination of zinc removal, or chelation, and broad spectrum antibiotic therapy was more effective than either approach on its own. These positive results supported development of the BioLexa Platform for multiple indications with *staph*-biofilms as the causative agent.

We intend to develop the BioLexa Platform for use in patients following the Section 505(b)(2) regulatory pathway of the FDA rules. Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FDCA") was enacted to enable sponsors to seek New Drug Application ("NDA") approval for novel repurposed drugs without the need for such sponsors to undertake time consuming and expensive pre-clinical safety studies and Phase 1 safety studies. Proceeding under this regulatory pathway, we will be able to rely upon publicly available data with respect to gentamicin and zinc chelator in our NDA submission to the FDA for marketing approval.

In September 2018, we attended the first of a series of meetings with the FDA to review the requirements for submission and activation of an investigational new drug application ("IND") with respect to the BioLexa Platform for use in eczema. We prepared and presented to the FDA our proposed first in human clinical trial plan for the treatment of eczema in patients over the age of one year old, and the FDA provided us with general guidance with respect to specific animal studies, dosing schedules and suggested human safety studies before we commence clinical trials in pediatric or adult patients. The FDA requested that safety and efficacy of BioLexa be established in adults prior to investigating pediatric and adolescent patients. Therefore, we planned to conduct our first clinical trial for BioLexa in Australia in order to enroll both adult and adolescents to support future clinical development.

On December 9, 2020, we received approval from the Belberry Human Research Ethics Committee ("HREC") in Australia to conduct our clinical trial of BioLexa, and we have engaged Novotech (Australia) Pty Limited ("Novotech") as our local clinical research organization in Australia to provide clinical management, data management, biostatistical, medical monitoring, pharmacovigilance, and other related services to support the first in human clinical trial of BioLexa. Phase 1 of the trial was initiated in 2021 and is expected to conclude in 2022.

We believe that the key elements for our market success with respect to BioLexa include:

- the proprietary formulation of two FDA-approved drugs to treat bacterial proliferation which may reduce development time and costs by giving us the ability to rely on safety and efficacy data from the two approved drugs;

- our proprietary formulation is not a topical corticosteroid, and provides a novel mechanism of action and potentially a preferred safety profile as a market differentiator; and

- the literature set forth below reaffirms the critical role that *S. aureus* plays in the development of atopic dermatitis flare-ups within the international medical community, supporting the targeted mechanism of action of BioLexa.

    Shi et al, "MRSA Colonization is Associated with Decreased Skin Commensal Bacteria in Atopic Dermatitis," Invest Dermatol. 2018.

    Blicharz, et al, "Staphylococcus aureus: an underestimated factor in the pathogenesis of atopic dermatitis?," Adv Dermatol Allergol 2019.

**Preclinical Development**

***HT-003***

On July 30, 2020 (the "Isoprene Effective Date"), we entered into a Sublicense Agreement (the "Isoprene Sublicense Agreement") with Isoprene Pharmaceuticals, Inc. ("Isoprene") pursuant to the commercial evaluation sublicense and option agreement dated March 8, 2019 by and among us, the University of Maryland, Baltimore and Isoprene. Pursuant to the Isoprene Sublicense Agreement, Isoprene granted us an exclusive sublicense to certain intellectual property (i) to make, have made, use, sell, offer to sell and import certain licensed products, (ii) in connection therewith, to use certain inventions and licensed materials and (iii) to practice certain patent rights for the treatment of dermatological conditions or diseases, referred to as HT-003. The retinoic acid metabolism blocking agents ("RAMBAs") have the potential to be developed as a platform for multiple inflammatory-based indications. Accordingly, we entered into a Sublicense Agreement with Isoprene on July 2, 2021 pursuant to the option agreement dated December 22, 2020 to expand the therapeutic indication of the sublicensed RAMBAs from Isoprene to include inflammatory bowel diseases, including Crohn's disease and ulcerative colitis.

Retinoids, which include Vitamin A (retinol) and its analogues (both synthetic and metabolites), play a critical role in cell signaling and biological processes, including regulation of immune cells and inflammation, signaling pathways that control normal skin maintenance, embryonic development and cell growth/differentiation/repair. Deficiencies in retinoids and their active metabolites have been implicated in a wide variety of diseases. In the skin, retinol deficiency leads to hyperkeratosis and keratinizing metaplasia that is observed in skin disorders like psoriasis and acne. Vitamin A and retinoic acid also play a crucial role in regulating cell proliferation, differentiation, and apoptosis and therefore, altered metabolism of retinoids has been suspected as playing a potential role in tumorigenesis. Accordingly, retinoids have been approved in the U.S. for treatment of acne and psoriasis as well as other therapeutic indications such as acute promyelocytic leukemia and cutaneous T-cell lymphoma; however, the therapeutic use of exogenous retinoids has been limited due to negative effects associated with high systemic concentrations. A new therapeutic approach to increase intracellular retinoic acid (the active metabolite of retinol) potentially without causing negative side effects of exogenous retinoic acid is to use inhibitors of RAMBAs, which prolong the presence of retinoic acid. HT-003 is a novel RAMBA under investigation for topical treatment in acne and psoriasis applications.

In December 2019, we entered into a research collaboration agreement with Weill Cornell Medicine for the completion of pre-clinical studies investigating the mechanism of action of HT-003 that was renewed in January 2021 as a result of positive preclinical results. Dr. Jonathan Zippin, M.D., Ph.D., FAAD, Associate Professor of Dermatology at Weill Cornell Medicine and our Senior Scientific Advisor, is the principal investigator for such pre-clinical studies.

Preclinical proof-of-concept studies began in the first quarter of 2021 for the investigation of RAMBAs for treatment of inflammatory bowel diseases, including Crohn's disease and ulcerative colitis.

***HT-004***

On November 20, 2019, we entered into a license agreement with North Carolina State University ("NC State") pursuant to which NC State granted us an exclusive license to, among other things, develop, make, use, offer and sell certain licensed products throughout the world with respect to HT-004 for treating allergic diseases. HT-004 is a potential disease-modifying agent that uses exon-skipping oligonucleotide-targeted methods to reduce mast cell responses to immunoglobulin E (IgE)-directed antigens, which is one of the key mechanisms in the pathophysiology of asthma, atopic dermatitis and other allergic diseases. HT-004 is currently under investigation for the treatment of asthma and allergies using inhalational administration.

Preclinical proof-of-concept data was generated in October 2020 supporting efficacy of HT-004 after inhalational delivery in a mouse model. Critical proof-of-concept studies in a humanized mouse model are planned to be conducted in 2022. These studies are being conducted by our Scientific Advisory Board member, Dr. Glenn Cruse, at NC State.

We believe that the key elements for our market success with respect to HT-004 include:

- To our knowledge, there are currently no disease-modifying agents for asthma or allergy diseases;
- The active pharmaceutical ingredient in HT-004 is a novel molecular class that we believe would prevent generic competition after commercialization;
- HT-004 is being developed for inhalational administration by either inhaler or nebulizer for easy access at home by patients; and
- HT-004 is applicable for both adult and pediatric patient populations with asthma and/or allergies.

***HT-006***

On December 22, 2020, we entered into a non-exclusive commercial evaluation license agreement with the U.S. Army Medical Research and Development Command ("USAMRDC"), as amended, pursuant to which USAMRDC granted us a non-exclusive commercial evaluation license to HT-006 for the treatment of lung diseases resulting from bacterial infections. We will initially target treatment of serious bacterial infections of the lung, such as hospital-acquired pneumonia ("HAP") and ventilator-associated pneumonia ("VAP"). Given the indication, we intend to develop HT-006 for inhalational administration.

Both HAP and VAP are considered life-threatening diseases for which current treatment options are limited or not effective against multi-drug resistance bacteria. As such, we intend to pursue streamlined development opportunities under the FDA's program for "antibacterial therapies for patients with an unmet medical need for the treatment of serious bacterial diseases." This streamlined program allows for the use of nonclinical animal studies to reduce clinical studies required for approval.

***HT-002***

On May 18, 2020, we entered into an Exclusive License Agreement with the Virginia Commonwealth University Intellectual Property Foundation ("VCU") pursuant to which VCU granted us an exclusive, royalty bearing license to HT-002, a novel peptide developed by researchers at VCU that may be used to slow the transmission of SARS-CoV-2 (the "VCU Peptide") and a non-exclusive royalty bearing, worldwide license with respect to certain licensed technical information patents to make, have made, use, offer to sell, sell and import certain licensed products and perform certain licensed services. On June 29, 2020, we entered into a Sponsored Project Agreement ("VCU SPA") with VCU for the development of a potential COVID-19 treatment using the VCU Peptide. The VCU SPA was amended on April 28, 2021 to extend the period of research and to add additional scope of investigation to include the variants of SARS-CoV-2.

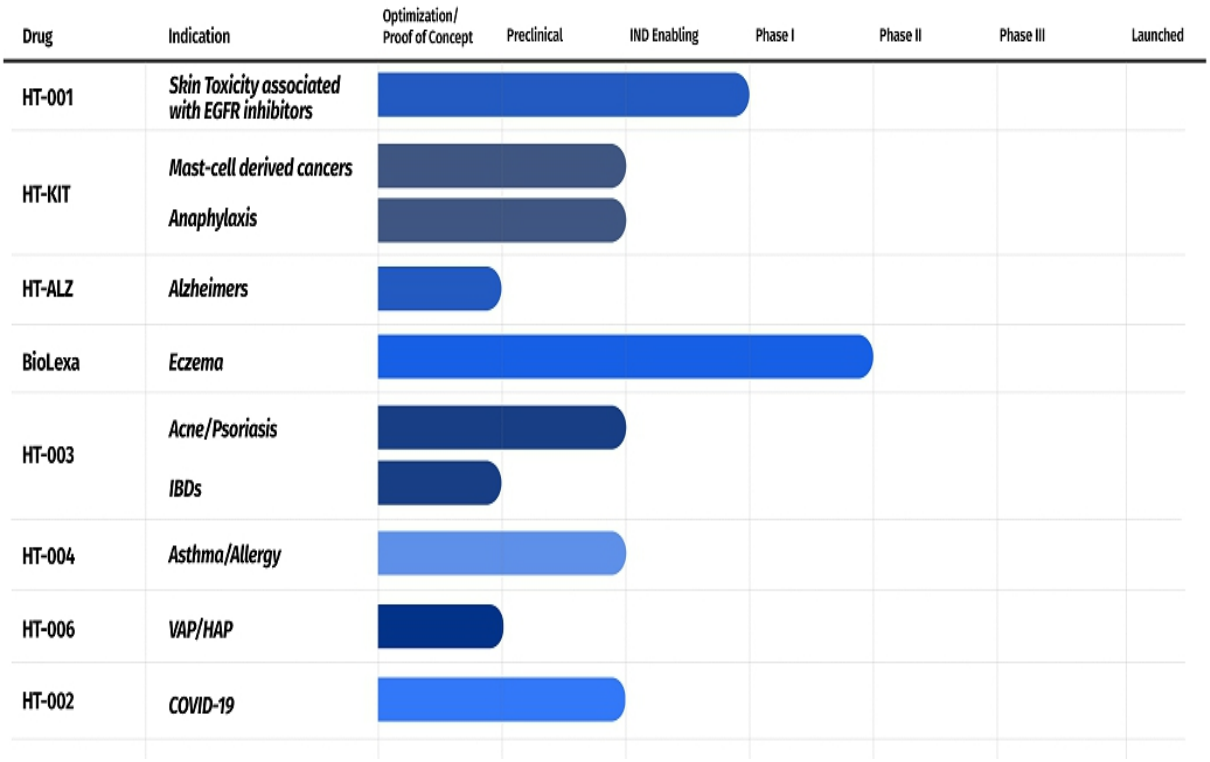
Proof-of-Concept preclinical studies are expected to be completed in 2022.

***Direct Detect Breath Diagnostic Device***

On August 7, 2020, we entered into a Patent License Agreement ("GW Patent License Agreement") with GW pursuant to which GW granted us an exclusive, worldwide, royalty bearing license to certain intellectual property that can be used to develop a device designed to detect the presence of viruses. Specifically, the GW Patent License Agreement permits us to make, have made, use, import, offer for sale and sell certain licensed products in the field of virus sensing and detection. We have engaged a company to develop a platform prototype and, once developed, we will select target analytes for further development.

**Product Development Pipeline**

The following table summarizes our product development pipeline.




**Other Interests**

We have interests in certain other assets being developed by third parties. Specifically, in December 2021, we entered into a license agreement with Zylö Therapeutics, Inc. ("Zylö") with respect to the development of HT-005. We had previously entered into a sublicense agreement with Zylö pursuant to which we had advanced the development of HT-005 for patients with lupus. (See Note 6 to the consolidated financial statements for a discussion of our agreement with Zylö). In addition, in March 2020, we entered into a Royalty and Development Agreement (the "Voltron Agreement") with Voltron Therapeutics, Inc. with respect to the development of potential product candidates for the prevention of COVID-19. (See Note 6 to the consolidated financial statements for a discussion of our agreement with Voltron).

**Competition**

The biopharmaceutical industry utilizes rapidly advancing technologies and is characterized by intense competition. There is also a strong emphasis on intellectual property and proprietary products. In the segment of the biopharmaceutical industry, competition from different sources including major biopharmaceutical companies, academic institutions, government agencies, and public and private research institutions will continue. Many of our competitors have significantly greater financial resources and expertise in product candidate development and may have progressed further toward approval and marketing. In addition, smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

**Manufacturing and Supply**

We do not have any manufacturing capability and therefore we currently rely on and intend to continue to rely on contract manufacturing organizations to produce our product candidates in accordance with regulatory requirements.

**Commercialization**

Our success depends not only on the successful development and approval of our products candidates but also on the commercialization of our potential products. If and when our product candidates receive regulatory approval, we intend to engage third-parties such as pharmaceutical and biotechnology companies for the commercialization of our products.

**Intellectual Property Portfolio**

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the U.S. and in other countries. Our policy is to actively seek the broadest intellectual property protection possible for our products, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world. In addition, we intend to actively pursue product life-cycle management initiatives to extend our market exclusivity.

We intend to cement our market exclusivity in conjunction with our formulation-development partners through additional patents based on the pharmaceutical and clinical characteristics of our product candidates in the proprietary formulation and through the introduction of line extensions such as combination drugs and new formulations.

In addition to any granted patents, our products may be eligible for market exclusivity to run concurrently with the term of the patent for three and a half years in the U.S. pursuant to the Hatch-Waxman Act and pediatric exclusivity guideline and up to ten years of market exclusivity in the E.U. which includes eight years of data exclusivity and two years of market exclusivity from the date we file an NDA or the European equivalent referred to as Marketing Authorization Application.

We currently have licenses to six U.S. patents and one pending U.S. patent application, and we have licenses to three patents issued in Europe and Australia and five pending patent applications in foreign jurisdictions including Europe, Brazil, Canada and Hong Kong. Hoth also holds two pending U.S. patent applications and one pending PCT patent application.

In addition to patents, we rely on trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We take measures to protect and maintain the confidentiality of proprietary information in order to protect aspects of the business that are not amenable to, or that we do not consider appropriate for, patent protection. We require employees, consultants, outside scientific partners, sponsored researchers and other advisors to execute confidentiality agreements with us on or prior to the commencement of employment or consulting relationships with us.

**Government Regulations**

Governmental authorities in the U.S. and other countries extensively regulate the research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing of pharmaceutical products, including biological products, and medical devices, such as those being developed by us. In the U.S., the FDA regulates such products under the FDCA and the Public Health Services Act and implements related regulations. Failure to comply with applicable FDA requirements, both before and after approval, may subject us to administrative and judicial sanctions, such as a delay in approving or refusal by the FDA to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

***U.S. Food and Drug Administration Regulations***

United States Drug Development

In the United States, the FDA regulates drugs (including biological products, such as vaccines), medical devices and combinations of drugs and devices, or combination products, under the FDCA and its implementing regulations. These products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, requests for voluntary product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive pre-clinical laboratory tests, animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in accordance with an applicable IND and other clinical study related regulations, referred to as good clinical practice ("GCP"), to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission to the FDA of an NDA or biologics license application ("BLA");
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with the FDA's current good manufacturing practice ("cGMP") requirements;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA or BLA; and
- FDA review and approval of the NDA or BLA prior to any commercial marketing or sale.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The product is initially introduced into a small number of healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product is suspected or known to be unavoidably toxic, the initial human testing may be conducted in patients.
- Phase 2. Involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit relationship of the product and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 trials. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an Institutional Review Board ("IRB"), which oversees the conduct of clinical trials, can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the study. The clinical trial sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

FDA Review Process

The results of product development, pre-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug, or BLA for a biological product, requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of a substantial user fee, and the sponsor of an approved NDA or BLA is also subject to an annual program user fee; although a waiver of such fee may be obtained under certain limited circumstances.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA's goal to complete its substantive review of a standard NDA and respond to the applicant is ten months from the receipt of the NDA. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification and may go through multiple review cycles.

The review and evaluation of an NDA or BLA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States, and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA or BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 clinical trials to further assess drug safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals, including the requirement for a risk evaluation and mitigation strategy ("REMS"), to assure the safe use of the drug.

***Section 505(b)(2) Regulatory Approval Pathway***

Section 505(b)(2) of the FDCA provides an alternate regulatory pathway for approval of a new drug by allowing the FDA to rely on data not developed by the applicant. Specifically, Section 505(b)(2) permits the submission of an NDA where one or more of the investigations relied upon by the applicant for approval was not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and/or the FDA's findings of safety and effectiveness for an approved drug already on the market. Approval or submission of a 505(b)(2) application, like those for abbreviated new drugs ("ANDAs"), may be delayed because of patent and/or exclusivity rights that apply to the previously approved drug.

A 505(b)(2) application may be submitted for a new chemical entity ("NCE") when some part of the data necessary for approval is derived from studies not conducted by or for the applicant and when the applicant has not obtained a right of reference.

Section 505(b)(2) applications also may be entitled to marketing exclusivity if supported by appropriate data and information. Three-year new data exclusivity may be granted to the 505(b)(2) application if one or more clinical investigations conducted in support of the application, other than bioavailability/bioequivalence studies, were essential to the approval and conducted or sponsored by the applicant. Five years of marketing exclusivity may be granted if the application is for an NCE, and pediatric exclusivity is likewise available.

***Orange Book Listing and Paragraph IV Certification***

For NDA submissions, including those under Section 505(b)(2), applicants are required to list with the FDA certain patents with claims that cover the applicant's product. Upon approval, each of the patents listed in the application is published in *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the Orange Book. Any applicant who subsequently files an ANDA or 505(b)(2) NDA that references a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a Paragraph IV Certification.

If an applicant has provided a Paragraph IV Certification to the FDA, the applicant must also send notice of the Paragraph IV Certification to the holder of the NDA for the approved drug and the patent owner once the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to notice of the Paragraph IV Certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV Certification prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of 30 months from the date of the lawsuit, the applicant's successful defense of the suit, or expiration of the patent.

***United States Medical Device Regulation***

Medical devices, including diagnostic test devices, also are subject to extensive and rigorous regulation by the FDA under the FDCA, as well as other federal and state regulatory bodies in the United States, and laws and regulations of foreign authorities in other countries. FDA requirements specific to medical devices are wide ranging and govern, among other things, the design, development and manufacturing, human clinical trials, preclearance or approval, advertising and promotion, and product import and export. Unless an exemption applies, medical devices distributed in the United States must receive either premarket clearance under Section 510(k) of the FDCA or premarket approval of a premarket application ("PMA"). During the COVID-19 public health emergency, the FDA has authorized COVID-19 diagnostic tests under its Emergency Use Authorization authority. Medical devices are classified into one of three classes—Class I, Class II, or Class III—depending on the degree or risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. Medical devices deemed to pose relatively low risk are placed in either Class I or II. Class II devices generally require the manufacturer to submit a premarket notification under Section 510(k) of the FDCA requesting permission for commercial distribution. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices are placed in Class III requiring PMA approval.

***Reimbursement***

Potential sales of any of our product candidates, if approved, will depend, at least in part, on the extent to which such products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage and/or reducing reimbursements for medical products and services. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our future revenues and results of operations. Decreases in third-party reimbursement or a decision by a third-party payor to not cover a product candidate, if approved, or any future approved products could reduce physician usage of our products, and have a material adverse effect on our sales, results of operations and financial condition.

In the United States, the Medicare Part D program provides a voluntary outpatient drug benefit to Medicare beneficiaries for certain products. We do not know whether our product candidates, if approved, will be eligible for coverage under Medicare Part D, but individual Medicare Part D plans offer coverage subject to various factors such as those described above. Furthermore, private payors often follow Medicare coverage policies and payment limitations in setting their own coverage policies.

***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

***Healthcare Laws and Regulations***

Sales of our product candidates, if approved, or any other future product candidate will be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we might conduct our business. The healthcare laws and regulations that may affect our ability to operate include the following:

- The federal Anti-Kickback Statute makes it illegal for any person or entity to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is in exchange for or to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value.

- Federal false claims and false statement laws, including the federal civil False Claims Act, prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent.

- Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors or making any false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their implementing regulations, impose obligations on certain types of individuals and entities regarding the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information.

- The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Also, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the federal government's and/or pharmaceutical industry's voluntary compliance guidelines, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, as well as state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

***Australia***

Our first clinical trial for BioLexa will be conducted in Australia. The TGA and the National Health and Medical Research Council set the GCP requirements for clinical research in Australia, and compliance with these codes is mandatory. Australia has also adopted international codes, such as those promulgate by the International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH"). The ICH guidelines must be followed across all areas of clinical research, including those related to pharmaceutical quality, nonclinical and clinical data requirements and trial designs. The basic requirements for preclinical data to support a first-in-human trial under ICH guidelines are applicable in Australia. Requirements related to adverse event reporting in Australia are similar to those required in other major jurisdictions.

Clinical trials conducted using "unapproved therapeutic goods" in Australia, being those which have not yet been evaluated by the TGA for quality, safety and efficacy must occur pursuant to either the Clinical Trial Notification Scheme ("CTN Scheme") or the Clinical Trial Exemption Scheme ("CTX Scheme"). In each case, the trial is supervised by a HREC, an independent review committee set up under guidelines of the Australian National Health and Medical Research Council that ensures the protection of rights, safety and well-being of human subjects involved in a clinical trial. A HREC does this by reviewing, approving and providing continuing examination of trial protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects. A HREC reviews the scientific validity of the trial design, the balance of risk versus harm of the therapeutic good, the ethical acceptability of the trial process, and approves the trial protocol. The HREC is also responsible for monitoring the conduct of the trial.

The CTN Scheme broadly involves:

- completion of preclinical laboratory and animal testing;
- submission to a HREC, of all material relating to the proposed clinical trial, including the trial protocol;
- the institution or organization at which the trial will be conducted, referred to as the "Approving Authority", giving final approval for the conduct of the trial at the site, having regard to the advice from the HREC; and
- the investigator submitting a 'Notification of Intent to Conduct a Clinical Trial' form ("CTN Form") to the TGA. The CTN form must be signed by the sponsor, the principal investigator, the chairman of the HREC and a person responsible from the Approving Authority. The TGA does not review any data relating to the clinical trial however CTN trials cannot commence until the trial has been notified to the TGA.

Under the CTX Scheme:

- a sponsor submits an application to conduct a clinical trial to the TGA for evaluation and comment; and
- a sponsor must forward any comments made by the TGA Delegate to the HREC(s) at the sites where the trial will be conducted.

A sponsor cannot commence a trial under the CTX Scheme until written advice has been received from the TGA regarding the application and approval for the conduct of the trial has been obtained from an ethics committee and the institution at which the trial will be conducted.

The Therapeutic Goods Act 1989 (the Act) requires that medical products, including pharmaceuticals, imported into, supplied in, or exported from Australia be included in the Australian Register of Therapeutic Goods ("ARTG"). In order to obtain registration of the product on the ARTG:

- Sponsors must provide a product application containing adequate nonclinical data as well as data from adequate and well-controlled clinical trials that demonstrate the safety and efficacy of the therapeutic product;
- Sponsors also must provide information demonstrating that the manufacture and quality of the therapeutic product complies with the principles of cGMP;
- TGA then evaluates the application data, taking into account recommendations from an advisory committee, such as the Advisory Committee on Medicines, which makes recommendations to the TGA as to whether or not to grant approval to include the therapeutic product in the ARTG; and
- TGA must decide to include the therapeutic product on the ARTG.

**Employees**

As of March 28, 2022, we employed a total of 4 full-time employees, 1 employee consultant, and 1 part-time employee. We are not a party to any collective bargaining agreements. We believe that we maintain good relations with our employees.

**Our Corporate Information**

We were incorporated as a Nevada corporation on May 16, 2017. Our principal executive offices are located at 1 Rockefeller Plaza, Suite 1039, New York, New York 10020 and our telephone number is (646) 756-2997.

**Available Information**

Our website address is www.hoththerapeutics.com. The contents of, or information accessible through, our website are not part of this Annual Report on Form 10-K, and our website address is included in this document as an inactive textual reference only. We make our filings with the U.S. Securities and Exchange Commission ("SEC"), including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the SEC. The public may read and copy the materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Additionally, the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is www.sec.gov. The information contained in the SEC's website is not intended to be a part of this filing.

**ITEM 1A. RISK FACTORS**

*An investment in our common stock involves a high degree of risk. You should carefully consider the following risk factors and the other information in this Annual Report on Form 10-K before investing in our common stock. Our business and results of operations could be seriously harmed by any of the following risks. The risks set out below are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. If any of the following events occur, our business, financial condition and results of operations could be materially adversely affected. In such case, the value and trading price of our common stock could decline, and you may lose all or part of your investment.*

**Risks Related to Our Financial Position and Need for Capital**

***We have generated no revenue from commercial sales to date and our future profitability is uncertain.***

We were incorporated in May 2017 and have a limited operating history and our business is subject to all of the risks inherent in the establishment of a new business enterprise. Our likelihood of success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with development and expansion of a new business enterprise. Since inception, we have incurred losses and expect to continue to operate at a net loss for at least the next several years as we commence our research and development efforts, conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. Our net losses for the years ended December 31, 2021 and 2020 were $14,313,705 and $7,197,816, respectively, and our accumulated deficit as of December 31, 2021 and 2020 was $33,727,163 and $19,413,458, respectively. There can be no assurance that the products under development by us will be approved for sale in the U.S. or elsewhere. Furthermore, there can be no assurance that if such products are approved they will be successfully commercialized, and the extent of our future losses and the timing of our profitability are highly uncertain. If we are unable to achieve profitability, we may be unable to continue our operations.

***If we fail to obtain the capital necessary to fund our operations, we will be unable to continue or complete our product development and you will likely lose your entire investment.***

We will need to continue to seek capital from time to time to continue development of our product candidates. We cannot provide any assurances that any revenues that we may generate in the future will be sufficient to fund our ongoing operations. We believe that we will need to raise substantial additional capital to fund our operations and the development and commercialization of our product candidates.

Our business or operations may change in a manner that may consume available funds more rapidly than anticipated and substantial additional funding may be required to maintain operations, fund expansion, commercialize our product candidates, develop new or enhanced products, acquire complementary products, business or technologies or otherwise respond to competitive pressures and opportunities, such as a change in the regulatory environment or a change in preferred treatment modalities. In addition, we may need to accelerate the growth of our sales capabilities and distribution beyond what is currently envisioned, and this would require additional capital. However, we may not be able to secure funding on favorable terms, if at all.

If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale back or eliminate our research and development activities, clinical studies or operations. We may also be required to obtain funds through arrangements with collaborators, which arrangements may require us to relinquish rights to certain intellectual property, technologies or products that we otherwise would not consider relinquishing, including rights to future product candidates or certain major geographic markets. This could result in sharing revenues which we might otherwise retain for ourselves. Any of these actions may harm our business, financial condition and results of operations.

The amount of capital we may need depends on many factors, including the progress, timing and scope of our product development programs; the progress, timing and scope of our pre-clinical studies and clinical trials; the time and cost necessary to obtain regulatory approvals; the time and cost necessary to further develop manufacturing processes and arrange for contract manufacturing; our ability to enter into and maintain collaborative, licensing and other commercial relationships; and our partners' commitment of time and resources to the development and commercialization of our products.

***Even if we can raise additional funding, we may be required to do so on terms that are dilutive to you.***

The capital markets have been unpredictable in the recent past for unprofitable companies such as ours. The amount of capital that a company such as ours is able to raise often depends on variables that are beyond our control. As a result, we may not be able to secure financing on terms attractive to us, or at all. If we are able to consummate a financing arrangement, the amount raised may not be sufficient to meet our future needs. If adequate funds are not available on acceptable terms, or at all, our business, including our results of operations, financial condition and our continued viability will be materially adversely affected.

**Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization**

***We are dependent upon the clinical success of our licensed products and technologies. If we are unable to generate revenues from our licensed products and technologies, our ability to create shareholder value may be limited.***

We do not currently generate revenues from any of our product candidates, and we may not be successful in obtaining regulatory approvals to commence our clinical trials. If we do not obtain such approvals, the time in which we expect to commence clinical programs for our product candidates will be extended and such extension may increase our expenses and our need for additional capital. Moreover, there is no guarantee that our clinical trials will be successful or that we will continue clinical development in support of an approval from the regulatory agencies for any indication. We note that most drug candidates never reach the clinical stage and even those that do commence clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Therefore, our business currently depends entirely on the successful development, regulatory approval and commercialization of our product candidates, which may never occur.

***Although we have entered into the Voltron Agreement pursuant to which we and HaloVax intend to jointly develop products to prevent COVID-19, no assurance can be given as to when, if ever, we will be able to develop any products for such purpose and if developed that such products will be successfully commercialized.***

In March 2020, we entered into the Voltron Agreement pursuant to which we and HaloVax will work to jointly develop potential products candidates to prevent COVID-19; however, no assurance can be given as to when, if ever, we will be able to develop any products for such purpose. Furthermore, we are subject to risks including, but not limited to, the following with respect to the development of a treatment for COVID-19:

- the Emergency Use Authorization marketing approval processes of the FDA are lengthy, time consuming and inherently unpredictable, and we cannot guarantee that we will ever have a marketable product;

- we may encounter substantial delays in completing our clinical studies which in turn will require additional costs, or we may fail to demonstrate adequate safety and efficacy to the satisfaction of applicable regulatory authorities;

- conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit;

- to be commercially successful, physicians must be persuaded that using our products are effective alternatives to other existing therapies and treatments;

- we may depend on third parties for manufacturing our proposed product candidates and any conflicts with such partners could delay or prevent the development or commercialization of such product candidates;

- if third-party contract manufacturers upon whom we rely to formulate and manufacture our product candidates do not perform, fail to manufacture according to our specifications or fail to comply with strict regulations, our clinical studies could be adversely affected and the development of our product candidates could be delayed or terminated or we could incur significant additional expenses;

- adverse events involving our products may lead the FDA to delay or deny clearance for our products or result in product recalls that could harm our reputation, business and financial results; and

- if we fail to comply with healthcare regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected.

***If our joint venture with HaloVax, LLC ("HaloVax") is not successful or if we fail to realize the benefits we anticipate from such joint venture, we may not be able to capitalize on the full market potential of our potential products.***

In March 2020, we entered into the Voltron Agreement to form a joint venture entity named HaloVax to jointly develop potential product candidates for the prevention of the COVID-19. Pursuant to the terms of the Voltron Agreement we are entitled to receive sales-based royalties at low single digit percentages. In addition, in 2020, we purchased 6% of HaloVax's outstanding membership interests and shall contribute proceeds of the development of products to prevent COVID-19. If and to the extent we and HaloVax are unable to develop potential product candidates for the prevention of COVID-19, we will not be entitled to any sale-based royalties and the value of our ownership interest in HaloVax could decline in which case we may lose all or part of our investment in HaloVax.

While Voltron has agreed to cooperate and use commercially reasonable efforts to exchange information and resources that will lead to the development activities and established a Joint Development Committee consisting of seven members, two of which were selected by us, to plan, review, coordinate and oversee the performance of the development activities and timelines with respect to development activities, we have limited contractual rights to direct its activities. Moreover, we will not have any other control with respect to the operations of HaloVax. Therefore, HaloVax will have a greater influence with respect to its commercialization efforts and other operations. In general, our joint venture with HaloVax subjects us to a number of related risks including that:

- we may not receive sales-based royalties pursuant to the terms of the Voltron Agreement;
- we may not be successful in the development of any product candidates;
- HaloVax may not commit sufficient resources to the marketing and distribution of our products;
- HaloVax may infringe the intellectual property rights of third parties, which may expose us to litigation and other potential liability;
- disputes may arise between us and HaloVax that result in the delay or termination of the commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources including, but not limited to, disputes with respect to commercializing products upon terms mutually agreeable or beneficial to us and HaloVax;
- any products, if developed, will be sold or licensed on terms that are beneficial to us;
- HaloVax may not provide us with timely and accurate information regarding commercialization status or results, which could adversely impact our ability to manage our own commercialization efforts, accurately forecast financial results or provide timely information to our shareholders regarding our commercialization efforts; and
- if any product candidates are successfully developed that we will be able to commercialize such products upon terms mutually agreeable or beneficial to us and HaloVax.

***If HT-005 is not commercialized by Zylö or otherwise acquired by a third party, we may not be able to capitalize on the full market potential of our interests with respect to HT-005.***

In December 2021, we licensed HT-005 back to Zylö and are entitled to receive a low single digit percent of the net proceeds attributable to the sale of HT-005 to a third party, a low single digit percent of the net proceeds from the sale of HT-005 in the United States and Canada and their respective territories (collectively, the "Territory") and a low double digit percent of any royalty Zylö receives through the sublicense to a third party based on the net sales of HT-005 in the Territory. In connection with the license of HT-005 back to Zylö, we acquired 100,000 shares of Zylö's Class B common stock. As of December 31, 2021, we own 220,000 shares of Zylö's Class B common stock. If Zylö is unable to sell or otherwise commercialize HT-005, we will not be entitled to any proceeds or sale-based royalties and the value of our ownership interest in Zylö could decline in which case we may lose all or part of our investment in Zylö.

***The marketing approval process of the FDA is lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for the product candidates we intend to develop, our business may be substantially harmed.***

None of the product candidates we intend to develop have gained marketing authorization, approval or clearance in the U.S. or elsewhere, and we cannot guarantee that we will ever have marketable products. Our business is substantially dependent on our ability to complete the development of, obtain marketing approval for, and successfully commercialize our product candidates in a timely manner. We cannot commercialize our product candidates in the United States or elsewhere without first obtaining approval from regulatory agencies such as the FDA to market each product candidate. Our product candidates could fail to receive marketing approval for many reasons, including among others:

- the FDA or other regulatory agencies may disagree with the design or implementation of our clinical trials;

- the FDA could determine that we cannot rely on Section 505(b)(2) for any of our product candidates; and

- the FDA may determine that we have identified the wrong reference listed drug or drugs or that approval of our Section 505(b)(2) application for any of our product candidates is blocked by patent or non-patent exclusivity of the reference listed drug or drugs.

In addition, the process of seeking regulatory clearance or approval to market the product candidates we intend to develop is expensive and time consuming and, notwithstanding the effort and expense incurred, clearance or approval is never guaranteed. If we are not successful in obtaining timely clearance or approval of our product candidates from the FDA or other foreign regulatory agencies, we may never be able to generate significant revenue and may be forced to cease operations. The NDA process is costly, lengthy and uncertain. Any NDA application filed by us will have to be supported by extensive data, including, but not limited to, technical, pre-clinical, clinical, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the product for its intended use.

Obtaining clearances or approvals from the FDA and from regulatory agencies in other countries is an expensive and time-consuming process and is uncertain as to outcome. The FDA and other agencies could ask us to supplement our submissions, collect non-clinical data, conduct additional clinical trials or engage in other time-consuming actions, or it could simply deny our applications. In addition, even if we obtain an NDA approval or pre-market approvals in other countries, the approval could be revoked or other restrictions imposed if post-market data demonstrates safety issues or lack of effectiveness. We cannot predict with certainty how, or when, the FDA or other regulatory agencies will act. If we are unable to obtain the necessary regulatory approvals, our financial condition and cash flow may be adversely affected, and our ability to grow domestically and internationally may be limited. Additionally, even if cleared or approved, our products may not be approved for the specific indications that are most necessary or desirable for successful commercialization or profitability.

***We may encounter substantial delays in completing our clinical studies which in turn will require additional costs, or we may fail to demonstrate adequate safety and efficacy to the satisfaction of applicable regulatory authorities.***

It is impossible to predict if or when any of our product candidates will prove safe or effective in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching, or failing to reach, a consensus with regulatory agencies on study design;

- delays in reaching, or failing to reach, agreement on acceptable terms with a sufficient number of prospective contract research organizations ("CROs") and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- delays in obtaining required IRB or Ethics Committee ("EC") approval at each clinical study site;

- delays in recruiting a sufficient number of suitable patients to participate in our clinical studies;

- imposition of a clinical hold by regulatory agencies, after an inspection of our clinical study operations or study sites;

- failure by our CROs, other third parties or us to adhere to clinical study, regulatory or legal requirements;

- failure to perform in accordance with the FDA's GCP or applicable regulatory guidelines in other countries;
- delays in the testing, validation, manufacturing and delivery of sufficient quantities of our product candidates to the clinical sites;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- clinical study sites or patients dropping out of a study;
- delay or failure to address any patient safety concerns that arise during the course of a trial;
- unanticipated costs or increases in costs of clinical trials of our product candidates;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ECs of the institutions in which such trials are being conducted, by an independent Safety Review Board for such trial or by the FDA, Therapeutics Goods Administration ("TGA"), European Medicines Agency ("EMA"), or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, TGA, or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Any inability to successfully complete pre-clinical and clinical development could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions.

Clinical study delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The outcome of pre-clinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Further, pre-clinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval. If the results of our clinical studies are inconclusive or if there are safety concerns or adverse events associated with our other product candidates, we may:

- be delayed in obtaining marketing approval for our product candidates, if approved at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be required to change the way the product is administered;

- be required to perform additional clinical studies to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of a product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- be sued; or
- experience damage to our reputation.

Additionally, our product candidates could potentially cause other adverse events that have not yet been predicted. The inclusion of ill patients in our clinical studies may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using. As described above, any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and impair our ability to commercialize our products.

***If we are not able to obtain any required regulatory approvals for our product candidates, we will not be able to commercialize our product candidates and our ability to generate revenue will be limited.***

We must successfully complete clinical trials for our product candidates before we can apply for marketing approval. Even if we complete our clinical trials, it does not assure marketing approval. Our pre-clinical trials may be unsuccessful, which would materially harm our business. Even if our initial pre-clinical trials are successful, we are required to conduct clinical trials to establish our product candidates' safety and efficacy, before a marketing application (NDA or BLA or their foreign equivalents) can be filed with the FDA, the EMA, or comparable foreign regulatory authorities for marketing approval of our product candidates.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA, EMA, and other regulatory authorities in the United States, European Union, and other countries, where regulations differ from country to country. We are not permitted to market our product candidates as prescription pharmaceutical products in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. In the United States, the FDA generally requires the completion of clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA or other regulatory authorities and even fewer are eventually approved for commercialization. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities. If our development efforts for our product candidates, including regulatory approval, are not successful for their planned indications, or if adequate demand for our product candidates is not generated, our business will be materially adversely affected.

Our success depends on the receipt of regulatory approval and the issuance of such regulatory approvals is uncertain and subject to a number of risks, including the following:

- the results of nonclinical or toxicology studies may not support the filing of an IND or foreign equivalent for our product candidates;
- the FDA, EMA, or comparable foreign regulatory authorities or IRBs or ECs may disagree with the design or implementation of our clinical trials;
- we may not be able to provide acceptable evidence of our product candidates' safety and efficacy;

- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, EMA, or other regulatory agencies for marketing approval;
- the dosing of our product candidates in a particular clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our product candidates;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA, BLA or other marketing application or to obtain regulatory approval in the United States or elsewhere;
- the requirement for additional studies;
- the FDA, EMA, or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the approval policies or regulations of the FDA, EMA, or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval;
- the FDA, EMA, or comparable foreign regulatory authorities may disagree on the design or implementation of our clinical trials, including the methodology used in our studies, our chosen endpoints, our statistical analysis, or our proposed product indication;
- our failure to demonstrate to the satisfaction of the FDA, EMA, or comparable regulatory authorities that a product candidate is safe and effective for its proposed indication;
- we may fail to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- immunogenicity might affect a product candidate's efficacy and/or safety;
- the FDA, EMA, or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- data collected from clinical trials of our product candidates may be insufficient to support the submission and filing of a marketing application or to obtain marketing approval. For example, the FDA may require additional studies to show that our product candidates are safe or effective;
- we may fail to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies;
- there may be changes in the approval policies or regulations that render our nonclinical and clinical data insufficient for approval; or
- the FDA, EMA or comparable foreign regulatory authority may require more information, including additional nonclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program.

Failure to obtain regulatory approval for our product candidates for the foregoing, or any other reasons, will prevent us from commercializing our product candidates, and our ability to generate revenue will be materially impaired. We cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we intend to conduct in the future or that such trials will be successful. The FDA, EMA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or pre-clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of our product candidates.

We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third party CROs with expertise in this area to assist us in this process. Securing regulatory approvals to market a product requires the submission of pre-clinical, clinical, and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities and supporting information to the appropriate regulatory authorities for each therapeutic indication to establish a product candidate's safety and efficacy for each indication. Our product candidates may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory marketing approval for our product candidates in any indication will prevent us from commercializing our product candidates, and our ability to generate revenue will be materially impaired.

***If we are unable to submit an application for product candidate approval under Section 505(b)(2) of the FDCA or if we are required to generate additional data related to the safety and efficacy of a product candidate in order to obtain approval under Section 505(b)(2), we may be unable to meet our anticipated development and commercialization timelines.***

We may seek marketing authorization in the United States under Section 505(b)(2) of the FDCA which permits use of a marketing application, referred to as a 505(b)(2) application, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. The FDA interprets this to mean that an applicant may rely for approval on such data as that found in published literature or the FDA's finding of safety or effectiveness, or both, of a previously approved drug product owned by a third party. There is no assurance that the FDA would find third-party data relied upon by us in a 505(b)(2) application sufficient or adequate to support approval and may require us to generate additional data to support the safety and efficacy of a product candidate. Consequently, we may need to conduct substantial new research and development activities beyond those we currently plan to conduct. Such additional new research and development activities would be costly and time consuming and there is no assurance that such data generated from such additional activities would be sufficient to obtain approval.

If the data to be relied upon in a 505(b)(2) application is related to drug products previously approved by the FDA and covered by patents that are listed in the FDA's Orange Book, we would be required to submit with our 505(b)(2) application a Paragraph IV Certification in which we must certify that we do not infringe the listed patents or that such patents are invalid or unenforceable, and provide notice to the patent owner or the holder of the approved NDA. The patent owner or NDA holder would have 45 days from receipt of the notification of our Paragraph IV Certification to initiate a patent infringement action against us. If an infringement action is initiated, the approval of our NDA would be subject to a stay of up to 30 months or more while we defend against such a suit. Approval of our product candidates under Section 505(b)(2) may therefore be delayed until patent exclusivity expires or until we successfully challenge the applicability of those patents to our product candidates. Alternatively, we may elect to generate sufficient clinical data so that we would no longer need to rely on third-party data, which would be costly and time consuming and there would be no assurance that such data generated from such additional activities would be sufficient to obtain approval.

We may not be able to obtain shortened review of our applications, and the FDA may not agree that a product candidate qualifies for marketing approval. If we are required to generate additional data to support approval, we may be unable to meet anticipated or reasonable development and commercialization timelines, may be unable to generate the additional data at a reasonable cost, or at all, and may be unable to obtain marketing approval. If the FDA changes its interpretation of Section 505(b)(2) allowing reliance on data in a previously approved drug application owned by a third party, or there is a change in the law affecting Section 505(b)(2), this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit.

***We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.***

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as "orphan drugs." Under the Orphan Drug Act, the FDA may designate a drug candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or if the disease or condition affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing and making a drug product available in the United States for the type of disease or condition will be recovered from sales of the product.

Orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Additionally, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity. This means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in certain circumstances, including proving clinical superiority (i.e., another product is safer, more effective or makes a major contribution to patient care) to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity, or obtain approval for the same product but for a different indication than that for which the orphan product has exclusivity. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective.

***Modifications to our products may require new drug or device approvals.***

Once a particular product receives FDA approval or clearance, expanded uses or uses in new indications of our products may require additional human clinical trials and new regulatory approvals or clearances, including additional IND and NDA/BLA submissions or premarket approvals before we can begin clinical development, and/or prior to marketing and sales. If the FDA requires new clearances or approvals for a particular use or indication, we may be required to conduct additional clinical studies, which would require additional expenditures and harm our operating results. If the products are already being used for these new indications, we may also be subject to significant enforcement actions. Conducting clinical trials and obtaining clearances and approvals can be a time-consuming process, and delays in obtaining required future clearances or approvals could adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

***Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.***

Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population; the nature of the trial protocol; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical trial investigators; support staff; proximity of patients to clinical sites; ability to comply with the eligibility and exclusion criteria for participation in the clinical trial; and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our product candidates or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products.

***Additional delays to the completion of clinical studies may result from modifications being made to the protocol during the clinical trial, if such modifications are warranted and/or required by the occurrences in the given trial.***

Each modification to the protocol during a clinical trial has to be submitted to the FDA. This could result in the delay or halt of a clinical trial while the modification is evaluated. In addition, depending on the quantity and nature of the changes made, the FDA could take the position that the data generated by the clinical trial is not poolable because the same protocol was not used throughout the trial. This might require the enrollment of additional subjects, which could result in the extension of the clinical trial and the FDA delaying clearance or approval of a product. Any such delay could have a material adverse effect on our business and results of operations.

***There can be no assurance that the data generated from our clinical trials using modified protocols will be acceptable to FDA.***

There can be no assurance that the data generated using modified protocols will be acceptable to the FDA or that if future modifications during the trial are necessary, that any such modifications will be acceptable to the FDA. If the FDA believes that its prior approval is required for a particular modification, it can delay or halt a clinical trial while it evaluates additional information regarding the change.

Serious injury or death resulting from a failure of one of our drug candidates during clinical trials could also result in the FDA delaying our clinical trials or denying or delaying clearance or approval of a product candidate. Even though an adverse event may not be the result of the failure of our drug candidate, the FDA or an IRB could delay or halt a clinical trial for an indefinite period of time while an adverse event is reviewed, and likely would do so in the event of multiple such events.

Any delay or termination of our current or future clinical trials as a result of the risks summarized above, including delays in obtaining or maintaining required approvals from IRBs, delays in patient enrollment, the failure of patients to continue to participate in a clinical trial, and delays or termination of clinical trials as a result of protocol modifications or adverse events during the trials, may cause an increase in costs and delays in the filing of any product submissions with the FDA, delay the approval and commercialization of our products or result in the failure of the clinical trial, which could adversely affect our business, operating results and prospects.

***We rely on third parties to conduct our clinical trials and to assist us with pre-clinical development. If these third parties do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products.***

We do not have the ability to independently conduct our pre-clinical and clinical trials for our product candidates, and we must rely on third parties, such as CROs, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations, meet expected deadlines or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control. The occurrence of any of the foregoing may adversely affect our business, operating results and prospects.

***The future results of our current or future clinical trials may not support our product candidate claims or may result in the discovery of unexpected adverse side effects.***

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our drug candidate claims or that the FDA or foreign regulatory agencies will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our drug candidates are safe and effective for the proposed indicated uses. If the FDA or other regulatory agencies conclude that the clinical trials for any of our product candidates has failed to demonstrate safety and effectiveness, we would not receive clearance from the FDA or other regulatory agencies to market that product in the United States or internationally for the indications sought.

In addition, such an outcome could cause us to abandon the product candidate and might delay development of other product candidates. Any delay or termination of our clinical trials will delay the filing of any product submissions with the FDA and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate’s profile. In addition, our clinical trials may involve a relatively small patient population. Because of the small sample size, our results may not be indicative of future results.

***Even if our product candidates are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing FDA regulations or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.***

The manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for any product candidate for which we obtain regulatory approval will be subject to continued regulatory review, oversight and periodic inspections by the FDA. In particular, we and our suppliers are required to comply with FDA's Quality System Regulations and International Standards Organization ("ISO") regulations for the manufacture of our products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval. Regulatory bodies, such as the FDA, enforce these regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, enforcement actions by the FDA.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce the potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that the product promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we or our commercialization partners cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider such training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with adverse event and pharmacovigilance reporting requirements, including the reporting of adverse events which occur in connection with, and whether or not directly related to, our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to recall, replace or refund the cost of any product we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

***Our revenue stream will depend upon third-party reimbursement.***

The commercial success of our products in both domestic and international markets will be substantially dependent on whether third-party coverage and reimbursement is available for patients that use our products. However, the availability of insurance coverage and reimbursement for newly approved therapies is uncertain, and therefore, third-party coverage may be particularly difficult to obtain even if our products are approved by the FDA as safe and efficacious. Patients using existing approved therapies are generally reimbursed all or part of the product cost by Medicare or other third-party payors. Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs, and, as a result, they may not cover or provide adequate payment for these products. Submission of applications for reimbursement approval generally does not occur prior to the filing of an NDA for that product and may not be granted for as long as many months after NDA approval. In order to obtain reimbursement arrangements for these products, we or our commercialization partners may have to agree to a net sales price lower than the net sales price we might charge in other sales channels. The continuing efforts of government and third-party payors to contain or reduce the costs of healthcare may limit our revenue. Initial dependence on the commercial success of our products may make our revenues particularly susceptible to any cost containment or reduction efforts.

***Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain for such product candidates.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the Medicare Modernization Act ("MMA") changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our product candidates and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the "Health Care Reform Law") is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Health Care Reform Law revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the law imposed a significant annual fee on companies that manufacture or import branded prescription drug products.

The Health Care Reform Law remains subject to legislative efforts to repeal, modify or delay the implementation of the law. However, if the Health Care Reform Law is repealed or modified, or if implementation of certain aspects of the Health Care Reform Law are delayed, such repeal, modification or delay may materially adversely impact our business, strategies, prospects, operating results or financial condition. We are unable to predict the full impact of any repeal, modification or delay in the implementation of the Health Care Reform Law on us at this time. Due to the substantial regulatory changes that will need to be implemented by the Centers for Medicare & Medicaid Services and others, and the numerous processes required to implement these reforms, we cannot predict which healthcare initiatives will be implemented at the federal or state level, the timing of any such reforms, or the effect such reforms or any other future legislation or regulation will have on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce or eliminate our profitability.

***We are dependent on third parties for manufacturing and marketing of our proposed product candidates. If we are not able to secure favorable arrangements with such third parties, our business and financial condition could be harmed.***

We will not manufacture any of our proposed product candidates for commercial sale nor do we have the resources necessary to do so. In addition, we currently do not have the capability to market our drug products ourselves. In addition to our internal sales force efforts, we have contracted with and intend to continue to contract with specialized manufacturing companies to manufacture our proposed product candidates and partner with larger pharmaceutical companies for commercialization of our products. In connection with our efforts to commercialize our proposed product candidates, we will seek to secure favorable arrangements with third parties to distribute, promote, market and sell our proposed product candidates. If our internal sales force is unable to successfully distribute, market and promote our product candidates and we are not able to secure favorable commercial terms or arrangements with third parties for the distribution, marketing, promotion and sales of our proposed product candidates, we may have to retain promotional and marketing rights and seek to develop the commercial resources necessary to promote or co-promote or co-market certain or all of our proposed drug candidates to the appropriate channels of distribution in order to reach the specific medical market that we are targeting. We may not be able to enter into any partnering arrangements on this or any other basis. If we are not able to secure favorable partnering arrangements or are unable to develop the appropriate resources necessary for the commercialization of our proposed product candidates, our business and financial condition could be harmed. In addition, we will have to hire additional employees or consultants, since our current employees have limited experience in these areas. Sufficient employees with relevant skills may not be available to us. Any increase in the number of our employees would increase our expense level and could have an adverse effect on our financial position.

In addition, we, or our potential commercial partners, may not successfully introduce our proposed product candidates or such candidates may not achieve acceptance by patients, health care providers and insurance companies. Further, it is possible that we may not be able to secure arrangements to manufacture, market, distribute, promote and sell our proposed product candidates at favorable commercial terms that would permit us to make a profit. To the extent that corporate partners conduct clinical trials, we may not be able to control the design and conduct of these clinical trials.

***We may have conflicts with our partners that could delay or prevent the development or commercialization of our product candidates.***

We may have conflicts with our partners, such as conflicts concerning the interpretation of pre-clinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our partners, such partner may act in a manner that is averse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenues: unwillingness on the part of a partner to pay us milestone payments or royalties we believe are due to us under a collaboration; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the partner to cooperate in the development or manufacture of the product, including providing us with product data or materials; unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

***Even if we receive regulatory approval for any of our product candidates, we may not be able to successfully commercialize the product and the revenue that we generate from its sales, if any, may be limited.***

If approved for marketing, the commercial success of our product candidates will depend upon each product's acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance for any of our product candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience, dosing burden and ease of administration;

- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our product candidates, and the target patient population to try new therapies;
- efficacy of our product candidates compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our product candidates may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our product candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our product candidates in applicable therapeutic and vaccine guidelines;
- the effectiveness of our own or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in approved labeling from regulatory authorities;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement or government pricing approvals.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidates successfully. For example, if the approval process takes too long, we may miss market opportunities thereby giving other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our product candidates not commercially viable. For example, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve any of our product candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization for that indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals or require risk management plans or a REMS to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require a REMS for an approved product when new safety information emerges. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our product candidates. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our product candidates.

***Our products will face significant competition, and if they are unable to compete successfully, our business will suffer.***

Our product candidates face, and will continue to face, intense competition from large pharmaceutical companies, as well as academic and research institutions. We compete in an industry that is characterized by: (i) rapid technological change, (ii) evolving industry standards, (iii) emerging competition and (iv) new product introductions. Our competitors have and may develop products and technologies that will compete with our products and technologies. Because several competing companies and institutions have greater financial resources than us, they may be able to: (i) provide broader services and product lines, (ii) make greater investments in research and development and (iii) carry on larger research and development initiatives. Our competitors also have greater development capabilities than we do and have substantially greater experience in undertaking pre-clinical and clinical testing of products, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. They also have greater name recognition and better access to customers than us.

***Adverse events involving our products may lead the FDA or other regulatory agencies to delay or deny clearance for our products or result in product recalls that could harm our reputation, business and financial results.***

Once a product receives clearance or approval, the agency has the authority to require the recall of commercialized products in the event of adverse side effects, material deficiencies or defects in design or manufacture. With respect to the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the product would cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of adverse side effects, impurities or other product contamination, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. In addition, the FDA requires that certain classifications of recalls be reported to FDA within ten working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

***If we fail to comply with healthcare regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected.***

Sales of our product candidates, if approved, or any other future product candidate will be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we might conduct our business. The healthcare laws and regulations that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute makes it illegal for any person or entity to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is in exchange for or to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value.

- federal false claims and false statement laws, including the federal civil False Claims Act and the Civil Monetary Penalties Law ("CMPL"), prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent;

- HIPAA, created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors or making any false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their implementing regulations, impose obligations on certain types of individuals and entities regarding the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information; and

- The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Also, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the federal government's and/or pharmaceutical industry's voluntary compliance guidelines, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, as well as state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

The laws and regulations applicable to our business are complex, changing and often subject to varying interpretations. As a result, we may not be able to adhere to all applicable laws and regulations. Any violation or alleged violation of any of these laws or regulations by us could have a material adverse effect on our business, financial condition, cash flows and results of operations. We may be a party to various lawsuits, demands, claims, *qui tam* suits, government investigations and audits, of which any could result in, among other things, substantial financial penalties or awards against us, reputational harm, termination of relationships or contracts related to our business, mandated refunds, substantial payments made by us, required changes to our business practices, exclusion from future participation in Medicare and other healthcare programs and possible criminal penalties.

If we are found in violation of applicable laws or regulations, we could suffer severe consequences that would have a material adverse effect on our business, results of operations, financial condition, cash flows, reputation and stock price, including:

- suspension or termination of our participation in federal healthcare programs;
- criminal or civil liability, fines, damages or monetary penalties for violations of healthcare fraud and abuse laws, including the federal False Claims Act, CMPL, and Anti-Kickback Statute;
- enforcement actions by governmental agencies or claims for monetary damages by patients under federal or state patient privacy laws, including HIPAA;
- repayment of amounts received in violation of law or applicable payment program requirements, and related monetary penalties;
- mandated changes to our practices or procedures that materially increase operating expenses;
- imposition of corporate integrity agreements that could subject us to ongoing audits and reporting requirements as well as increased scrutiny of our business practices;
- termination of various relationships or contracts related to our business; and
- harm to our reputation which could negatively affect our business relationships, decrease our ability to attract or retain patients and physicians, decrease access to new business opportunities and impact our ability to obtain financing, among other things.

Responding to lawsuits and other proceedings as well as defending ourselves in such matters will continue to require management's attention and cause us to incur significant legal expense. It is also possible that criminal proceedings may be initiated against us or individuals in our business in connection with investigations by the federal government.

Furthermore, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

***If a third-party contract manufacturing organization ("CMO") upon whom we rely to formulate and manufacture our product candidates does not perform, fails to manufacture according to our specifications or fails to comply with strict regulations, our pre-clinical studies or clinical trials could be adversely affected, and the development of our product candidates could be delayed or terminated or we could incur significant additional expenses.***

We do not own or operate any manufacturing facilities. We rely on and intend to continue to rely on CMOs to formulate and manufacture our pre-clinical and clinical materials. Our reliance on a CMO exposes us to a number of risks, any of which could delay or prevent the completion of our pre-clinical studies or clinical trials, or the regulatory approval or commercialization of our product candidates, result in higher costs, or deprive us of potential product revenues. Some of these risks include:

- our CMO failing to develop an acceptable formulation to support later-stage clinical trials for, or the commercialization of, our product candidates;
- our CMO failing to manufacture our product candidate according to our specifications, the FDA's cGMP requirements, or otherwise manufacturing material that we or the FDA may deem to be unsuitable in our clinical trials;
- our CMO being unable to increase the scale of, increase the capacity for, or reformulate the form of our product candidates. We may experience a shortage in supply, or the cost to manufacture our products may increase to the point where it may adversely affect the cost of our product candidates. We cannot assure you that our CMO will be able to manufacture our product candidates at a suitable scale, or we will be able to find alternative manufacturers acceptable to us that can do so;
- our CMO placing a priority on the manufacture of their own products, or other customers' products;
- our CMO failing to perform as agreed upon or not remain in business; and
- our CMO's plants being closed as a result of regulatory sanctions, natural disasters, health epidemics or otherwise.

Manufacturers of pharmaceutical products are subject to ongoing periodic inspections by the FDA, the U.S. Drug Enforcement Administration and corresponding state and foreign agencies to ensure strict compliance with FDA mandated cGMPs, other government regulations and corresponding foreign standards. While we are obligated to audit their performance, we do not have control over our CMO's compliance with these regulations and standards. Failure by any of our CMOs, or us, to comply with applicable regulations could result in sanctions being imposed on us or the CMOs. These sanctions may include fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

***In the event that we need to change our CMOs, our pre-clinical studies, clinical trials or the commercialization of our product candidates could be delayed, adversely affected or terminated, or such a change may result in significantly higher costs.***

Various steps in the manufacture of our product candidates may need to be sole-sourced. In accordance with cGMP, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further pre-clinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing our current or future CMOs may be difficult for us and could be costly, which could result in our inability to manufacture our product candidates for an extended period of time and therefore a delay in the development of our product candidates. Further, in order to maintain our development time lines in the event of a change in our CMOs, we may incur significantly higher costs to manufacture our product candidates.

***Healthcare Reform in the United States.***

In the United States, there have been, and continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect the future results of pharmaceutical manufactures' operations. In particular, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. On the federal level, the Affordable Care Act ("ACA") was enacted in March 2010, and included measures to significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA that have been of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- implementation of the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act";
- a licensure framework for follow-on biologic products;
- creation of Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price;
- adoption of methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- creation of a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- expansion of the entities eligible for discounts under the Public Health program.

Although there have been legal and political challenges to certain aspects of the ACA, the Biden Administration has affirmed support for the law, entered its own executive orders to enforce and strengthen it, and committed to examining and, where appropriate, reversing contrary Trump Administration policies. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate."

Because of the volatility surrounding the implementation and enforcement of the ACA since its passage, and at this time, the full effect that the ACA would have on a pharmaceutical manufacturer remains unclear. This uncertainty is heightened by President Biden's January 28, 2021 Executive Order on Strengthening Medicaid and the Affordable Care Act which indicates that the Biden Administration may significantly modify the ACA and further reform the ACA and other federal programs in manner that may impact our operations. The Biden Administration has indicated that a goal of its administration is to expand and support Medicaid and the ACA and to make high-quality healthcare accessible and affordable. The potential increase in patients covered by government funded insurance may impact our pricing. Further, it is possible that the Biden Administration may further increase scrutiny of drug pricing.

Additionally, in December 2019, a federal appeals court held that the individual mandate portion of the ACA was unconstitutional and left open the question whether the remaining provisions of the ACA would be valid without the individual mandate. However, on appeal, the Supreme Court ruled in June 2021 that the parties challenging the law lacked standing, leaving the ACA in place. It is unclear how any other potential litigation challenging the ACA and the healthcare reform measures of the Biden administration will impact the ACA. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services.

Moreover, prescription drug pricing has been a recent focus of federal policymaking. The Trump Administration issued a series of executive orders and rules related to prescription drug pricing, including executive orders in July and September 2020 focused on reducing drug prices and rules in November 2020 establishing a 'Most Favored Nation' rule tying Medicare Part B drug pricing to prices in other countries, as well as a rule effectively banning rebates from Medicare Part D. The Biden Administration has indicated that lowering prescription drug prices is a priority for the Biden Administration as well.

Further, there is uncertainty surrounding the applicability of the biosimilars provisions under the ACA. The FDA has issued several guidance documents, but no implementing regulations, on biosimilars. A number of biosimilar applications have been approved over the past few years. The regulations that are ultimately promulgated and their implementation are likely to have considerable impact on the way pharmaceutical manufacturers conduct their business and may require changes to current strategies. A biosimilar is a biological product that is highly similar to an approved drug notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the approved drug in terms of the safety, purity, and potency of the product.

Individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm a pharmaceutical manufacturer's business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for certain products or put pressure product pricing, which could negatively affect a pharmaceutical manufacturer's business, results of operations, financial condition and prospects.

In addition, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. While no one cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm a pharmaceutical manufacturer's ability to generate revenue. Increases in importation or re-importation of pharmaceutical products from foreign countries into the United States could put competitive pressure on a pharmaceutical manufacturer's ability to profitably price products, which, in turn, could adversely affect business, results of operations, financial condition and prospects. A pharmaceutical manufacturer might elect not to seek approval for or market products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue generated from product sales. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

***Security threats to our information technology infrastructure and/or our physical buildings could expose us to liability and damage our reputation and business.***

It is essential to our business strategy that our technology and network infrastructure and our physical buildings remain secure and are perceived by our customers and corporate partners to be secure. Despite security measures, however, any network infrastructure may be vulnerable to cyber-attacks by hackers and other security threats. We may face cyber-attacks that attempt to penetrate our network security, sabotage or otherwise disable our research, products and services, misappropriate our or our customers' and partners' proprietary information, which may include personally identifiable information, or cause interruptions of our internal systems and services. Despite security measures, we also cannot guarantee security of our physical buildings. Physical building penetration or any cyber-attacks could negatively affect our reputation, damage our network infrastructure and our ability to deploy our products and services, harm our relationship with customers and partners that are affected, and expose us to financial liability.

Additionally, there are a number of state, federal and international laws protecting the privacy and security of health information and personal data. For example, HIPAA imposes limitations on the use and disclosure of an individual's healthcare information by healthcare providers, healthcare clearinghouses, and health insurance plans, or, collectively, covered entities, and also grants individuals rights with respect to their health information. HIPAA also imposes compliance obligations and corresponding penalties for non-compliance on individuals and entities that provide services to healthcare providers and other covered entities. As part of the American Recovery and Reinvestment Act of 2009 ("ARRA") the privacy and security provisions of HIPAA were amended. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. As amended by ARRA and subsequently by the final omnibus rule adopted in 2013, HIPAA also imposes notification requirements on covered entities in the event that certain health information has been inappropriately accessed or disclosed, notification requirements to individuals, federal regulators, and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by the U.S. Department of Health and Human Services. Most states have laws requiring notification of affected individuals and/or state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms, to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

**Risks Relating to Our Intellectual Property Rights**

***We rely upon licenses granted to us by various licensors, and if such licensors do not adequately defend such licenses, our business may be harmed.***

We have entered into and may, in the future, enter into license and sublicense agreements with respect to our product candidates. We have limited control over the activities of our licensors, and we rely upon our licensors to protect their intellectual property, including the patents covered by our licenses. We cannot be certain that activities conducted by our licensors have been or will be conducted in compliance with applicable laws and regulations. Furthermore, we have no or limited control or input over whether, and in what manner, our licensors may enforce or defend the patents that we license against a third-party. Our licensors may defend the patents we license less vigorously than if we had enforced or defended the patents ourselves. Furthermore, our licensors may not necessarily seek enforcement in scenarios in which we would feel that enforcement was in our best interests. For example, our licensors may not enforce the patents against a competitor of ours who is not a direct competitor of such licensor. If our in-licensed intellectual property is found to be invalid or unenforceable, then our licensors may not be able to enforce the patents against a competitor of ours. Moreover, if we fail to meet our obligations under our license agreements, the licensor may terminate the license agreement. Furthermore, if we fail to meet our obligations under our sublicense agreements or our sublicensor fails to meet its obligations to the licensor, such licensor may terminate the license agreement thereby terminating our sublicense agreement.

***Our business depends upon us securing and protecting critical intellectual property.***

Although we do not own and only license intellectual property, to the extent we develop intellectual property, our commercial success will depend in part on obtaining and maintaining patent, trade secret, copyright and trademark protection of our technologies in the United States and other jurisdictions as well as successfully enforcing and defending such intellectual property rights against third-party challenges. We will only be able to protect our intellectual property from unauthorized use by third parties to the extent that valid and enforceable intellectual property protection, such as patents or trade secrets, cover them. In particular, we place considerable emphasis on obtaining patent and trade secret protection for significant new technologies, products and processes. Furthermore, the degree of future protection of our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Moreover, the degree of future protection of our proprietary rights is uncertain for products that are currently in the early stages of development because we cannot predict which of these products will ultimately reach the commercial market or whether the commercial versions of these products will incorporate proprietary technologies.

***Patent positions in our industry are highly uncertain and involve complex legal and factual questions.***

Patent positions in our industry are highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. For example, we or our licensors might not have been the first to make the inventions covered by our pending patent applications and issued patents, as applicable; we or our licensors might not have been the first to file patent applications for these inventions; others may independently develop similar or alternative technologies or duplicate any of our technologies; it is possible that none of our pending patent applications or the pending patent applications of our licensors will result in issued patents; our issued patents and issued patents of our licensors may not provide a basis for commercially viable technologies, or may not provide us with any competitive advantages, or may be challenged and invalidated by third parties; and, we may not develop additional proprietary technologies that are patentable. As a result, our owned and licensed patents may not be valid, and we may not be able to obtain and enforce patents and to maintain trade secret protection for the full commercial extent of our technology. The extent to which we are unable to do so could materially harm our business.

We or our licensors have applied for and will continue to apply for patents for certain products. Such applications may not result in the issuance of any patents, and any patents now held or that may be issued may not provide us with adequate protection from competition. Furthermore, it is possible that patents issued or licensed to us may be challenged successfully. In that event, if we have a preferred competitive position because of such patents, any preferred position held by us would be lost. If we are unable to secure or to continue to maintain a preferred position, we could become subject to competition from the sale of generic products. Failure to receive, inability to protect, or expiration of our patents for medical use, manufacture, conjugation and labeling of any of our product candidates may adversely affect our business and operations.

Patents issued or licensed to us may be infringed by the products or processes of others. The cost of enforcing our patent rights against infringers, if such enforcement is required, could be significant, and we do not currently have the financial resources to fund such litigation. Further, such litigation can go on for years and the time demands could interfere with our normal operations. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. We may become a party to patent litigation and other proceedings. The cost to us of any patent litigation, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation more effectively than we can because of their substantially greater financial resources. Litigation may also absorb significant management time.

Unpatented trade secrets, improvements, confidential know-how and continuing technological innovation are important to our scientific and commercial success. Although we attempt to and will continue to attempt to protect our proprietary information through reliance on trade secret laws and the use of confidentiality agreements with our corporate partners, collaborators, employees and consultants and other appropriate means, these measures may not effectively prevent disclosure of our proprietary information, and, in any event, others may develop independently, or obtain access to, the same or similar information.

***If we are found to be infringing on patents or trade secrets owned by others, we may be forced to cease or alter our product development efforts, obtain a license to continue the development or sale of our products, and/or pay damages.***

Our manufacturing processes and potential products may violate proprietary rights of patents that have been or may be granted to competitors, universities or others, or the trade secrets of those persons and entities. As the pharmaceutical industry expands and more patents are issued, the risk increases that our processes and potential products may give rise to claims that they infringe the patents or trade secrets of others. These other persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the affected product or process. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to conduct clinical tests, manufacture or market the affected product or use the affected process. Required licenses may not be available on acceptable terms, if at all, and the results of litigation are uncertain. If we become involved in litigation or other proceedings, it could consume a substantial portion of our financial resources and the efforts of our personnel.

***Our ability to protect and enforce any patents we may obtain does not guaranty that we will secure the right to commercialize such patents.***

A patent is a limited monopoly right conferred upon an inventor, and his successors in title, in return for the making and disclosing of a new and non-obvious invention. This monopoly is of limited duration but, while in force, allows the patent holder to prevent others from making and/or using his invention. While a patent gives the holder this right to exclude others, it is not a license to commercialize the invention, where other permissions may be required for permissible commercialization to occur. For example, a drug cannot be marketed without the appropriate authorization from the FDA, regardless of the existence of a patent covering the product. Further, the invention, even if patented itself, cannot be commercialized if it infringes the valid patent rights of another party.

***We rely on confidentiality agreements to protect our trade secrets. If these agreements are breached by our employees or other parties, our trade secrets may become known to our competitors.***

We rely on trade secrets which we seek to protect through confidentiality agreements with our employees and other parties. If these agreements are breached, our competitors may obtain and use our trade secrets to gain a competitive advantage over us. We may not have any remedies against our competitors and any remedies that may be available to us may not be adequate to protect our business or compensate us for the damaging disclosure. In addition, we may have to expend resources to protect our interests from possible infringement by others.

**Related Risks to the Company**

***We have expanded and may continue to expand, our business through the acquisition of rights to new drug candidates that could disrupt our business, harm our financial condition and may also dilute current shareholders' ownership interests in our Company.***

Our business strategy includes expanding our products and capabilities, and we may seek acquisitions of additional drug candidates or technologies to do so. Acquisitions involve numerous risks, including substantial cash expenditures; potentially dilutive issuance of equity securities; incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition; difficulties in assimilating the acquired technologies or the operations of the acquired companies; diverting our management's attention away from other business concerns; risks of entering markets in which we have limited or no direct experience; and the potential loss of our key employees or key employees of the acquired companies.

We cannot assure you that any acquisition will result in short-term or long-term benefits to us. We may misjudge the value or worth of an acquired product, company or business. In addition, our future success would depend in part on our ability to manage the rapid growth associated with acquisitions. We cannot assure you that we will be able to make the combination of our business with that of acquired products, businesses or companies work or be successful. Furthermore, the development or expansion of our business or any acquired products, business or companies may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our preferred or common stock, which could dilute each current shareholder's ownership interest in the Company.

***Any international operations we undertake may subject us to risks inherent with operations outside of the United States.***

We may seek to obtain market clearance for in foreign markets that we deem to generate significant opportunities. However, even with the cooperation of a commercialization partner, conducting drug development in foreign countries involves inherent risks, including, but not limited to: difficulties in staffing, funding and managing foreign operations; unexpected changes in regulatory requirements; export restrictions; tariffs and other trade barriers; difficulties in protecting, acquiring, enforcing and litigating intellectual property rights; fluctuations in currency exchange rates; and potentially adverse tax consequences. If we were to experience any of the difficulties listed above, or any other difficulties, our international development activities and our overall financial condition may suffer and cause us to reduce or discontinue our international development and registration efforts.

***We may not be successful in hiring and retaining key employees, including executive officers.***

Our future operations and successes depend in large part upon the strength of our management team. We rely heavily on the continued service of each member of our management team. Accordingly, if any member of our management team were to terminate their employment with us, such departure may have a material adverse effect on our business. In addition, our future success depends on our ability to identify, attract, hire or engage, retain and motivate other well-qualified financial, managerial, technical, clinical and regulatory personnel. There can be no assurance that these professionals will be available in the market, or that we will be able to retain existing professionals or to meet or to continue to meet their compensation requirements. Furthermore, the cost base in relation to such compensation, which may include equity compensation, may increase significantly, which could have a material adverse effect on us. Failure to establish and maintain an effective management team and work force could adversely affect our ability to operate, grow and manage our business.

***Managing our growth as we expand operations may strain our resources.***

We expect to grow rapidly in order to support additional, larger, and potentially international, pivotal clinical trials of our drug candidates, which will place a significant strain on our financial, managerial and operational resources. In order to achieve and manage growth effectively, we must continue to improve and expand our operational and financial management capabilities. Moreover, we will need to increase staffing and to train, motivate and manage our employees. All of these activities will increase our expenses and may require us to raise additional capital sooner than expected. Failure to manage growth effectively could harm our business, financial condition or results of operations.

***If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business.***

The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We currently do not have product liability insurance coverage but we intend to obtain such insurance. Such insurance coverage may not protect us against any or all of the product liability claims that may be brought against us in the future. We may not be able to acquire or maintain adequate product liability insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. In the event our product candidate is approved for sale by the FDA or other regulatory agency and commercialized, we may need to substantially increase the amount of our product liability coverage. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business.

***Our business may be adversely affected by the ongoing coronavirus pandemic.***

The outbreak of the novel Coronavirus (COVID-19) evolved into a global pandemic. The coronavirus has spread to many regions of the world. The extent to which the coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus, including variants, and the actions to contain the coronavirus or treat its impact, among others.

Should the coronavirus continue to spread, our business operations could be delayed or interrupted. For instance, our clinical trials may be affected by the pandemic. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. If the coronavirus continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Further, if the spread of the coronavirus pandemic continues and our operations are adversely impacted, we risk a delay, default and/or nonperformance under existing agreements which may increase our costs. These cost increases may not be fully recoverable or adequately covered by insurance.

Infections and deaths related to the pandemic may disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA review and/or approval with respect to, our clinical trials. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

We currently utilize third parties to, among other things, manufacture raw materials. If any third parties in the supply chain for materials used in the production of our product candidates are adversely impacted by restrictions resulting from the coronavirus outbreak, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials and research and development operations.

In the event of a shelter-in-place order or other mandated local travel restrictions, our employees conducting research and development, or manufacturing activities may not be able to access their laboratory or manufacturing space, and our core activities may be significantly limited or curtailed, possibly for an extended period of time.

The spread of the coronavirus, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on our business. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the situation closely.

**Risks Related to Our Common Stock**

***The price of our common stock may fluctuate substantially.***

You should consider an investment in our common stock to be risky, and you should invest in our common stock only if you can withstand a significant loss and wide fluctuations in the market value of your investment. Some factors that may cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, are:

- sale of our common stock by our shareholders, executives, and directors;
- volatility and limitations in trading volumes of our shares of common stock;

- our ability to obtain financings to conduct and complete research and development activities including, but not limited to, our clinical trials, and other business activities;
- the timing and success of introductions of new products by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors;
- our ability to attract new customers;
- our ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;
- commencement, enrollment or results of our clinical trials for our product candidates;
- changes in the development status of our product candidates;
- any delays or adverse developments or perceived adverse developments with respect to a regulatory agency's review of our planned pre-clinical and clinical trials;
- any delay in our submission for studies or product approvals or adverse regulatory decisions, including failure to receive regulatory approval for our product candidates;
- unanticipated safety concerns related to the use of our product candidates;
- changes in our capital structure or dividend policy, future issuances of securities and sales of large blocks of common stock by our shareholders;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new products;
- reputational issues;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new products, capital commitments, or other events by us or our competitors;
- changes in general economic, political and market conditions in or any of the regions in which we conduct our business;
- changes in industry conditions or perceptions;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigations related to intellectual properties, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control, including, but not limited to, pandemics such as COVID-19, war, or other acts of God.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

***We may acquire other companies or technologies, which could divert our management's attention, result in dilution to our shareholders and otherwise disrupt our operations and adversely affect our operating results.***

We may in the future seek to acquire or invest in businesses, applications and services or technologies that we believe could complement or expand our services, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated.

In addition, we do not have any experience in acquiring other businesses. If we acquire additional businesses, we may not be able to integrate the acquired personnel, operations and technologies successfully, or effectively manage the combined business following the acquisition. We also may not achieve the anticipated benefits from the acquired business due to a number of factors, including:

- inability to integrate or benefit from acquired technologies or services in a profitable manner;
- unanticipated costs or liabilities associated with the acquisition;
- difficulty integrating the accounting systems, operations and personnel of the acquired business;
- difficulties and additional expenses associated with supporting legacy products and hosting infrastructure of the acquired business;
- difficulty converting the customers of the acquired business onto our platform and contract terms, including disparities in the revenue, licensing, support or professional services model of the acquired company;
- diversion of management's attention from other business concerns;
- adverse effects to our existing business relationships with business partners and customers as a result of the acquisition;
- the potential loss of key employees;
- use of resources that are needed in other parts of our business; and
- use of substantial portions of our available cash to consummate the acquisition.

In addition, a significant portion of the purchase price of companies we acquire may be allocated to acquired goodwill and other intangible assets, which must be assessed for impairment at least annually. In the future, if our acquisitions do not yield expected returns, we may be required to take charges to our operating results based on this impairment assessment process, which could adversely affect our results of operations. Acquisitions could also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial position may suffer.

***Market and economic conditions may negatively impact our business, financial condition and share price.***

Concerns over inflation, energy costs, geopolitical issues, the U.S. mortgage market and a declining real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

***If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports about our business, our stock price and trading volume may decline.***

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our common stock, the lack of research coverage may adversely affect the market price of our common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

***Future sales and issuances of our securities could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to fall.***

We expect that significant additional capital will be needed in the future to continue our planned operations, including research and development, increased marketing, hiring new personnel, commercializing our products, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our shareholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to our existing shareholders.

***We do not intend to pay cash dividends on our shares of common stock so any returns will be limited to the value of our shares.***

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to shareholders will therefore be limited to the increase, if any, of our share price.

***We are an "emerging growth company" and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.***

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended ("Sarbanes-Oxley"), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. In addition, pursuant to Section 107 of the JOBS Act, as an "emerging growth company" we intend to take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of our initial public offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

***We may be at risk of securities class action litigation.***

We may be at risk of securities class action litigation. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

***If we fail to comply with the continued listing requirements of The Nasdaq Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.***

On December 30, 2021, we received written notice from the Nasdaq Stock Market, LLC ("Nasdaq") that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price of our common stock had been below $1.00 per share for 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810, we have a period of 180 calendar days, or until June 28, 2022, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for at least 10 consecutive business days during this 180 calendar day period. In the event we do not regain compliance by June 28, 2022, we may be eligible for an additional 180 calendar day grace period if we meet the continued listing standards, with the exception of bid price, for The Nasdaq Capital Market, and we provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period. Although we may effect a reverse stock split of our issued and outstanding common stock in the future, there can be no assurance that such reverse stock split will enable us to regain compliance with the Nasdaq minimum bid price requirement.

***Financial reporting obligations of being a public company in the United States are expensive and time-consuming, and our management will be required to devote substantial time to compliance matters.***

As a publicly traded company we incur significant legal, accounting and other expenses. The obligations of being a public company in the United States require significant expenditures and places significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under Sarbanes-Oxley, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the listing requirements of The Nasdaq Capital Market. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company." Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

***If we fail to comply with the rules under Sarbanes-Oxley related to internal controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal controls over financial reporting, our stock price could decline significantly and raising capital could be more difficult.***

Section 404 of Sarbanes-Oxley requires annual management assessments of the effectiveness of our internal controls over financial reporting. If we fail to comply with the rules under Sarbanes-Oxley related to disclosure controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal controls over financial reporting, our stock price could decline significantly and raising capital could be more difficult. If material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal controls, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of Sarbanes-Oxley. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly.

***Our Articles of Incorporation, as amended ("Articles of Incorporation"), our Amended and Restated Bylaws, and Nevada law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.***

Our Articles of Incorporation, Amended and Restated Bylaws, and Nevada law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our shareholders. We are authorized to issue up to 10,000,000 shares of preferred stock, none of which are outstanding as of March 28, 2022. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by shareholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. As of March 28, 2022, 5,000,000 shares of our preferred stock have been designated as Series A Preferred Stock of which 3,102,480 shares of Series A Preferred Stock were previously issued and converted into common stock at the time of our initial public offering and 1,897,520 shares of Series A Preferred Stock remain authorized. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our Articles of Incorporation, our Amended and Restated Bylaws and Nevada law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a shareholder might consider favorable. Such provisions may also prevent or frustrate attempts by our shareholders to replace or remove our management. In particular, the Articles of Incorporation, our Amended and Restated Bylaws and Nevada law, as applicable, among other things:

- provide the board of directors with the ability to alter the Amended and Restated Bylaws without shareholder approval;
- place limitations on the removal of directors;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at shareholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

***Our Amended and Restated Bylaws provide that the Eighth Judicial District Court of Clark County, Nevada will be the sole and exclusive forum for certain disputes which could limit shareholders' ability to obtain a favorable judicial forum for disputes with us or its directors, officers, employees or agents.***

Our Amended and Restated Bylaws provide that unless we consent in writing to the selection of an alternative forum, the Eighth Judicial District Court of Clark County, Nevada shall be the sole and exclusive forum for state law claims with respect to: (i) any derivative action or proceeding brought in the name or right of us or on our behalf, (ii) any action asserting a claim for breach of any fiduciary duty owed by any director, officer, employee or agent to us or our shareholders, (iii) any action arising or asserting a claim arising pursuant to any provision of Nevada Revised Statutes Chapters 78 or 92A or any provision of our Articles of Incorporation or Amended and Restated Bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine, including, without limitation, any action to interpret, apply, enforce or determine the validity of our Articles of Incorporation or Amended and Restated Bylaws. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

This choice of forum provision may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, other employees or agents and may result in increased costs to our shareholders, which may discourage such lawsuits against us and our directors, officers, other employees and agents. Alternatively, if a court were to find the choice of forum provision contained in our Amended and Restated Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, results of operations, and financial condition.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Our executive office is located at 1 Rockefeller Plaza, Suite 1039, New York, NY 10020. We lease our office for approximately $4,500 per month pursuant to a lease which terminates on July 31, 2022. We believe that our existing facilities are suitable and adequate to meet our current needs. We intend to add new facilities or expand existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

**ITEM 3. LEGAL PROCEEDINGS**

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

**Market Information**

On February 15, 2019, our common stock began trading on The Nasdaq Capital Market under the symbol "HOTH." Prior to that time, there was no public market for our common stock.

**Shareholders**

As of March 28, 2022, there were 139 shareholders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders, and includes shareholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include shareholders whose shares may be held in trust by other entities.

**Dividend Policy**

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors that our board of directors deems relevant.

**Recent Sales of Unregistered Securities**

None.

### ITEM 6. [RESERVED]

### ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITIONS AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with and our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Annual Report on Form 10-K. All amounts in this report are in U.S. dollars, unless otherwise noted.*

**Overview**

We are a clinical-stage biopharmaceutical company focused on developing new generation therapies for unmet medical needs. We are focused on developing (i) a topical formulation for treating side effects from drugs used for the treatment of cancer (HT-001); (ii) a treatment for mast-cell derived cancers and anaphylaxis (HT-KIT); and (iii) a treatment and/or prevention for Alzheimer's or other neuroinflammatory diseases (HT-ALZ). We also have preclinical assets being developed for (i) atopic dermatitis (also known as eczema) (BioLexa);(ii) a treatment for asthma and allergies using inhalational administration (HT-004); (iii) a treatment for lung diseases resulting from bacterial infections (HT-006); and (iv) a treatment for inflammatory bowel diseases (HT-003). In addition, we are developing a diagnostic device via a mobile device. We also have interests in certain other assets being developed by third parties including HT-005 for patients with lupus that is being developed by Zylö and potential product candidates being developed pursuant to our agreement with Voltron for the prevention of COVID-19.

**Results of Operations**

**Comparison of Our Results of Operations for the Years Ended December 31, 2021 and 2020**

***Operating Costs and Expenses***

***Research and Development Expenses***

For the year ended December 31, 2021, research and development expenses were approximately $7.5 million, of which approximately $0.2 million was related to licenses acquired and approximately $7.4 million was related to other research and development expenses.

For the year ended December 31, 2020, research and development expenses were approximately $2.9 million, of which approximately $0.6 million was related to licenses acquired and approximately $2.3 million was related to other research and development expenses.

We expect our research and development activities to increase as we develop our existing product candidates and potentially acquire new product candidates, reflecting increasing costs associated with the following:

- employee-related expenses, which include salaries and benefits, and rent expenses;
- fees related to in-licensed products and technology;
- expenses incurred under agreements with CROs, investigative sites and consultants that conduct our clinical trials and a substantial portion of our pre-clinical activities;
- the cost of acquiring and manufacturing clinical trial materials; and
- costs associated with non-clinical activities and regulatory approvals.

***Compensation, Professional Fees, Rent and Other ("General and Administrative Expenses")***

For the year ended December 31, 2021, General and Administrative Expenses were approximately $6.6 million, which primarily consisted of approximately $3.0 million related to payroll expenses and stock-based compensation, approximately $2.7 million for professional fees and approximately $0.8 million for other expenses.

For the year ended December 31, 2020, General and Administrative Expenses were approximately $4.4 million, which primarily consisted of approximately $1.5 million related to payroll expenses and stock-based compensation, approximately $2.5 million for professional fees and approximately $0.5 million for other expenses.

We anticipate that our General and Administrative expenses will increase in future periods, reflecting continued and increasing costs associated with:

- support of our research and development activities;
- stock compensation granted to key employees and non-employees;
- support of business development activities; and
- increased professional fees and other costs associated with the regulatory requirements.

***Other Income (Expenses)***

For the year ended December 31, 2021, other expenses were approximately $0.2 million, which consisted of the realized gain or loss, unrealized gain or loss, and dividend income related to marketable securities.

For the year ended December 31, 2020, other income was approximately $0.1 million, which consisted of the realized gain or loss, unrealized gain or loss, and dividend income related to marketable securities.

**Liquidity and Capital Resources**

We have incurred substantial operating losses since inception and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2021, we had approximately $8.5 million in cash, marketable securities of $1.9 million, current liabilities of $0.9 million and an accumulated deficit of approximately $33.7 million.

We have entered into certain license, sublicense, sponsored research and option agreements with third parties. Pursuant to such agreements, we may be required make certain: (i) license maintenance fee payments; (ii) out-of-pocket expense payments, including, but not limited to, payments related to intellectual property and research related expenses; (iii) development and commercialization expense payments; (iv) annual and quarterly minimum payments; (v) diligence expense payments; and (vi) revenue interest payments. In addition, subject to the achievement of certain development and/or commercialization events, we may also be required to make certain: (i) minimum royalty payments, ranging from middle to high five figures, (ii) sales-based royalties and running royalties, ranging from low single digits to low double digits; and (iii) milestone payments, of up to approximately $21 million (if all milestones in all of our current agreements are achieved). See Note 3 to the consolidated financial statements for discussion of our agreements with third parties.

We have funded our operations from proceeds from the sale of equity and debt securities. We will require significant additional capital to make the investments we need to execute our longer-term business plan. Our ability to successfully raise sufficient funds through the sale of debt or equity securities when needed is subject to many risks and uncertainties and, even if it were successful, future equity issuances would result in dilution to our existing shareholders and future debt securities may contain covenants that limit our operations or ability to enter into certain transactions.

We believe our current cash is sufficient to fund operations for at least the next 12 months from the date that our audited financial statements are available to be issued. However, we will need to raise additional funding through strategic relationships, public or private equity or debt financings, grants or other arrangements to develop and seek regulatory approvals for our existing and new product candidates. If such funding is not available, or not available on terms acceptable to us, our current development plan and plans for expansion of our general and administrative infrastructure may be curtailed.

***Cash Flows from Operating Activities***

For the year ended December 31, 2021, net cash used in operations was approximately $12.1 million, which primarily resulted from a net loss of approximately $14.3 million, and was partially offset by changes in operating assets and liabilities of approximately $0.5 million, unrealized loss on marketable securities of approximately $0.2 million, and approximately $1.3 million stock-based compensation.

For the year ended December 31, 2020, net cash used in operations was approximately $6.1 million, which primarily resulted from a net loss of approximately $7.2 million and changes in operating assets and liabilities of approximately $0.1 million, partially offset by approximately $0.5 million research and development expense related to license acquisitions and $0.7 million of stock-based compensation.

***Cash Flows from Investing Activities***

For the year ended December 31, 2021, net cash used in investing activities was approximately $0.2 million, which was primarily related to the sale of marketable securities of approximately $2.5 million, and was partially offset by the purchase of marketable securities of approximately $2.6 million.

For the year ended December 31, 2020, net cash used in investing activities was approximately $1.8 million, which was primarily related to the purchase of marketable securities of approximately $2.3 million and purchase of investments in HaloVax, LLC and Zylö of approximately $0.4 million, partially offset by the sale of marketable securities of approximately $1.1 million.

***Cash Flows from Financing Activities***

For the year ended December 31, 2021, net cash provided by financing activities was approximately $18.2 million. The cash provided by financing activities primarily resulted from approximately $17.8 million in net proceeds from the issuance of common stock, common stock warrants and pre-funded warrants, and $0.4 million in proceeds from the exercise of warrants.

For the year ended December 31, 2020, net cash provided by financing activities was approximately $8.7 million. The cash provided by financing activities primarily resulted from approximately $8.7 million in net proceeds from the issuance of common stock and warrants.

Our ultimate success is dependent on our ability to obtain additional financing and generate sufficient cash flow to meet our obligations on a timely basis. We will require significant amounts of capital to sustain operations, and we will need to make the investments we need to execute our longer-term business plan to support new technologies and help advance innovation. Absent generation of sufficient revenue from the execution of our long-term business plan, we will need to obtain debt or equity financing, especially if we experience downturns in our business that are more severe or longer than anticipated, or if we experience significant increases in expense levels resulting from being a publicly traded company or from operations. Such additional debt or equity financing may not be available to us on favorable terms, if at all.

We plan to pursue our plans with respect to the research and development of our pre-clinical products which will require resources beyond those that we currently have, ultimately requiring additional capital from third party sources. We currently do not expect to generate any revenue.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the balance sheet and the reported amounts of expenses during the reporting period. In accordance with GAAP, we evaluate our estimates and judgments on an ongoing basis. The most significant estimates relate to the valuation of stock options and the valuation allowance of deferred tax assets resulting from net operating losses. We base our estimates and assumptions on current facts, our limited historical experience and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those accounting principles that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in Annual Report on Form 10-K, we believe the following are the critical accounting policies used in the preparation of our consolidated financial statements that require significant estimates and judgments:

*Stock-based compensation*

We expense stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. We record the expense for stock-based compensation awards subject to performance-based milestone vesting over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the expected satisfaction of the performance conditions at each reporting date. All stock-based compensation costs are recorded in general and administrative or research and development costs in the statements of operations based upon the underlying employees' or non-employees' roles.

*Income taxes*

Income taxes are recorded in accordance with Accounting Standards Codification ("ASC") 740, Income Taxes ("ASC 740") which provides for deferred taxes using an asset and liability approach. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in our consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between our financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We account for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

**Significant Accounting Policies**

See Note 2 to the consolidated financial statements for a discussion of recent accounting policies.

**JOBS Act**

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have chosen to take advantage of the extended transition periods available to emerging growth companies under the JOBS Act for complying with new or revised accounting standards until those standards would otherwise apply to private companies provided under the JOBS Act. As a result, our consolidated financial statements may not be comparable to those of companies that comply with public company effective dates for complying with new or revised accounting standards.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including, without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of Sarbanes-Oxley and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of our initial public offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

As a smaller reporting company, we are not required to provide the information required by this item.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**Hoth Therapeutics, Inc.**
**Consolidated Financial Statements**

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## Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of
Hoth Therapeutics, Inc.

**Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheets of Hoth Therapeutics, Inc. (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of operations, changes in stockholders' equity and cash flows, for each of the two years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2021 and 2020, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/S/ WithumSmith+Brown, PC

We have served as the Company's auditor since 2018.

New York, New York
March 29, 2022
PCAOB ID No. 100

**Hoth Therapeutics, Inc.**
**Consolidated Balance Sheets**

| | December 31, 2021 | December 31, 2020 |
|---|---|---|
| **ASSETS** | | |
| Current assets | | |
| Cash | $ 8,538,270 | $ 2,629,670 |
| Marketable equity securities, at fair value | 1,892,837 | 2,063,236 |
| Prepaid expenses | 93,972 | 89,836 |
| Note receivable - current | 50,000 | - |
| Total current assets | 10,575,079 | 4,782,742 |
| Note receivable | - | 50,000 |
| Investment in joint venture at fair value | 410,000 | 410,000 |
| **Total assets** | **$ 10,985,079** | **$ 5,242,742** |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities | | |
| Accounts payable | $ 360,964 | $ 129,469 |
| Accrued expenses | 426,823 | 128,180 |
| Accrued license fee - current portion | 80,000 | 54,500 |
| Total current liabilities | 867,787 | 312,149 |
| Accrued license fee - less current portion | 235,000 | 285,000 |
| **Total liabilities** | **1,102,787** | **597,149** |
| **Commitments and contingencies** | - | - |
| **Stockholders' equity** | | |
| Preferred stock, $0.0001 par value, 5,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2021 and 2020, respectively | - | - |
| Series A Convertible Preferred Stock, $0.0001 par value, 5,000,000 shares designated; 0 shares issued and outstanding at December 31, 2021 and 2020 | - | - |
| Common stock, $0.0001 par value, 75,000,000 shares authorized, 23,974,546 and 13,438,535 shares issued and outstanding at December 31, 2021 and 2020, respectively | 2,398 | 1,343 |
| Additional paid-in-capital | 43,589,471 | 24,073,059 |
| Accumulated deficit | (33,727,163) | (19,413,458) |
| Accumulated other comprehensive gain (loss) | 17,586 | (15,351) |
| Total stockholders' equity | 9,882,292 | 4,645,593 |
| **Total liabilities and stockholders' equity** | **$ 10,985,079** | **$ 5,242,742** |

*The accompanying notes are an integral part of these consolidated financial statements.*

**Hoth Therapeutics, Inc.**
**Consolidated Statements of Operations and Comprehensive Loss**

| | For the years ended December 31, | |
|---|---|---|
| | **2021** | **2020** |
| Operating costs and expenses | | |
| Research and development | $ 7,354,708 | $ 2,281,363 |
| Research and development - licenses acquired (including stock-based compensation) | 174,782 | 607,562 |
| Compensation and related expenses (including stock-based compensation) | 3,036,034 | 1,454,478 |
| Professional fees (including stock-based compensation) | 2,703,837 | 2,478,493 |
| Rent | 46,871 | 25,871 |
| Other general and administrative expenses | 785,208 | 454,207 |
| Total operating expenses | 14,101,440 | 7,301,974 |
| Loss from operations | (14,101,440) | (7,301,974) |
| | | |
| Other income (expenses) | | |
| Other income (expenses), net | (212,265) | 104,158 |
| Total other income (expenses) | (212,265) | 104,158 |
| | | |
| **Net loss** | **$ (14,313,705)** | **$ (7,197,816)** |
| Other comprehensive gain (loss) | | |
| Foreign currency translation adjustment | 32,937 | (15,351) |
| **Total comprehensive loss** | **$ (14,280,768)** | **$ (7,213,167)** |
| | | |
| Net loss per share applicable to common stockholders - basic and diluted | $ (0.64) | $ (0.58) |
| Weighted average number of common shares outstanding, basic and diluted | 22,330,093 | 12,362,833 |

*The accompanying notes are an integral part of these consolidated financial statements.*

**Hoth Therapeutics, Inc.**
**Consolidated Statements of Changes in Stockholders' Equity**

| | Common Stock | | Additional Paid-in | Accumulated | Cumulative Translation | Total Stockholders' |
|---|---|---|---|---|---|---|
| | Shares | Amount | Capital | Deficit | Adjustment | Equity |
| **Balance at December 31, 2019** | **10,119,844** | **$ 1,012** | **$14,610,638** | **$ (12,215,642)** | **$ -** | **$ 2,396,008** |
| Issuance of common stock and warrants (net of offering costs of $806,243) | 1,449,275 | 145 | 4,193,611 | - | - | 4,193,756 |
| Issuance of common stock (net of offering costs of $525,000) | 1,818,182 | 182 | 4,474,818 | - | - | 4,475,000 |
| Cancellation of common stock | (15,000) | (2) | 2 | - | - | - |
| Warrant exercise | 56,250 | 6 | 56,244 | - | - | 56,250 |
| Stock-based compensation | 9,984 | - | 737,746 | - | - | 737,746 |
| Cumulative translation adjustment | - | - | - | - | (15,351) | (15,351) |
| Net loss | - | - | - | (7,197,816) | - | (7,197,816) |
| **Balance at December 31, 2020** | **13,438,535** | **$ 1,343** | **$24,073,059** | **$ (19,413,458)** | **$ (15,351)** | **$ 4,645,593** |
| Issuance of common stock, common stock warrants and prefunded warrants (net of offering costs of $1,591,600) | 6,826,962 | 683 | 13,406,949 | - | - | 13,407,632 |
| Issuance of common stock and warrants (net of offering costs of $572,500) | 2,475,248 | 248 | 4,427,253 | - | - | 4,427,501 |
| Warrant exercise | 1,126,720 | 113 | 359,400 | - | - | 359,513 |
| Stock-based compensation | 107,081 | 11 | 1,322,810 | - | - | 1,322,821 |
| Cumulative translation adjustment | - | - | - | - | 32,937 | 32,937 |
| Net loss | - | - | - | (14,313,705) | - | (14,313,705) |
| **Balance at December 31, 2021** | **23,974,546** | **$ 2,398** | **$43,589,471** | **$ (33,727,163)** | **$ 17,586** | **$ 9,882,292** |

*The accompanying notes are an integral part of these consolidated financial statements.*

**Hoth Therapeutics, Inc.**
**Consolidated Statements of Cash Flows**

| | For the years ended December 31, | |
|---|---|---|
| | **2021** | **2020** |
| **Cash flows from operating activities** | | |
| Net loss | $ (14,313,705) | $ (7,197,816) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation expense | - | 1,043 |
| Research and development-acquired license, expensed | 92,470 | 506,957 |
| Stock-based compensation | 1,322,821 | 737,746 |
| Realized loss (gain) on marketable securities | 41,808 | 1,177 |
| Unrealized loss (gain) on marketable securities | 176,974 | (50,553) |
| Loss on foreign currency exchange | 59,583 | - |
| Changes in assets and liabilities: | | |
| Prepaid expenses | (5,420) | 20,236 |
| Accounts payable | 535,340 | (151,988) |
| Net cash used in operating activities | (12,090,129) | (6,133,198) |
| | | |
| **Cash flows from investing activities** | | |
| Purchase of investments in joint venture | - | (410,000) |
| Purchase of research and development licenses | (116,970) | (167,457) |
| Purchase of marketable securities | (2,556,135) | (2,300,015) |
| Purchase of convertible promissory note in Isoprene | - | (50,000) |
| Sale of marketable securities | 2,507,750 | 1,089,819 |
| Net cash used in investing activities | (165,355) | (1,837,653) |
| | | |
| **Cash flows from financing activities** | | |
| Proceeds from issuance common stock, common stock warrants and prefunded warrants, net of offering cost | 13,407,632 | - |
| Proceeds from issuance common stock and warrants, net of offering cost | 4,427,501 | 4,193,756 |
| Proceeds from issuance common stock, net of offering cost | - | 4,475,000 |
| Proceeds from exercise of warrants | 359,513 | 56,250 |
| Net cash provided by financing activities | 18,194,646 | 8,725,006 |
| | | |
| Effect of exchange rate changes on cash and cash equivalents | (30,562) | (15,351) |
| | | |
| Net change in cash | 5,939,162 | 754,155 |
| Cash, beginning of period | 2,629,670 | 1,890,866 |
| | | |
| Cash, end of period | $ 8,538,270 | $ 2,629,670 |
| | | |
| **Non-cash investing and financing activities** | | |
| Cancellation and retirement of common stock | $ - | $ 2 |

*The accompanying notes are an integral part of these consolidated financial statements.*

**Note 1—Organization and description of business operations**

Hoth Therapeutics, Inc. (together with its wholly-owned subsidiary, Hoth Therapeutics Australia Pty Ltd., the "Company") was incorporated under the laws of the State of Nevada on May 16, 2017. The Company is a clinical-stage biopharmaceutical company focused on developing new generation therapies for unmet medical needs. The Company is focused on developing (i) a topical formulation for treating side effects from drugs used for the treatment of cancer; (ii) a treatment for mast-cell derived cancers and anaphylaxis; and (iii) a treatment and/or prevention for Alzheimer's or other neuroinflammatory diseases. The Company also has preclinical assets being developed for (i) atopic dermatitis (also known as eczema); (ii) a treatment for asthma and allergies using inhalational administration; (iii) a treatment for lung diseases resulting from bacterial infections; and (iv) a treatment for inflammatory bowel diseases. In addition, the Company is developing a diagnostic device via a mobile device. The Company also has interests in certain other assets being developed by third parties (See Note 6 for a discussion of the Company's agreement with Zylö Therapeutics, Inc. and Voltron Therapeutics, Inc.).

***Liquidity and capital resources***

Accounting Standards Update ("ASU") No. 2014-15, *Presentation of Financial Statements - Going Concern*, requires management to evaluate the Company's ability to continue as a going concern one year beyond the filing date of the given financial statements. This evaluation requires management to perform two steps. First, management must evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern. Second, if management concludes that substantial doubt is raised, management is required to consider whether it has plans in place to alleviate that doubt. Disclosures in the notes to the consolidated financial statements are required if management concludes that substantial doubt exists or that its plans alleviate the substantial doubt that was raised.

The Company has funded its operations from proceeds from the sale of equity and debt securities. The Company will require significant additional capital to make the investments it needs to execute its longer-term business plan. The Company's ability to successfully raise sufficient funds through the sale of debt or equity securities when needed is subject to many risks and uncertainties and, even if it were successful, future equity issuances would result in dilution to its existing stockholders and future debt securities may contain covenants that limit the Company's operations or ability to enter into certain transactions.

The Company's current cash is sufficient to fund operations for at least the next 12 months from the date that these financial statements are available to be issued. However, the Company will need to raise additional funding through strategic relationships, public or private equity or debt financings, grants or other arrangements to develop and seek regulatory approvals for the Company's existing and new product candidates. If such funding is not available, or not available on terms acceptable to the Company, the Company's current development plan and plans for expansion of its general and administrative infrastructure may be curtailed.

**Note 2—Significant accounting policies**

***Basis of presentation and principles of consolidation***

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP").

The accompanying consolidated financial statements include the accounts of the Company's wholly-owned subsidiary, Hoth Therapeutics Australia Pty Ltd, which was incorporated under the laws of the State of Victoria in Australia on June 5, 2019. All significant intercompany balances and transactions have been eliminated in consolidation.

***Emerging growth company***

As an emerging growth company, the Company may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the Jumpstart Our Business Startups Act of 2012 ("JOBS Act") exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act of 1933, as amended, registration statement declared effective or do not have a class of securities registered under the Securities Exchange Act of 1934, as amended) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company's financial statement with another public company that is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

***Use of estimates***

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. The most significant estimates in the Company's consolidated financial statements relate to stock-based compensation and the valuation allowance of deferred tax assets resulting from net operating losses. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

***Cash and cash equivalents***

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. There were no cash equivalents as of December 31, 2021 and 2020.

***Marketable securities***

Marketable securities are classified as trading and are carried at fair value. The Company's marketable securities consist of a mutual fund which is valued at a quoted market price.

***Concentrations of credit risk and off-balance sheet risk***

Cash is a financial instrument that is potentially subject to concentrations of credit risk. The Company's cash is deposited in accounts at large financial institutions, and amounts may exceed federally insured limits. The Company believes it is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash is held. The Company has no financial instruments with off-balance sheet risk of loss.

***Fair Value of Financial Instruments***

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 820, *Fair Value Measurements*, provides guidance on the development and disclosure of fair value measurements. Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance classifies fair value measurements in one of the following three categories for disclosure purposes:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

In some circumstances, the inputs used to measure fair value might be categorized within different levels of the fair value hierarchy. In those instances, the fair value measurement is categorized in its entirety in the fair value hierarchy based on the lowest level input that is significant to the fair value measurement.

***Fair value option – Note receivable***

The guidance in ASC 825, *Financial Instruments*, provides a fair value option election that allows entities to make an irrevocable election of fair value as the initial and subsequent measurement attribute for certain eligible financial assets and liabilities. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. The decision to elect the fair value option is determined on an instrument-by-instrument basis and must be applied to an entire instrument and is irrevocable once elected. Assets and liabilities measured at fair value pursuant to this guidance are required to be reported separately in the Company's consolidated balance sheets from those instruments using another accounting method.

***Investment in joint venture***

Ownership interests in entities for which the Company has significant influence that are not consolidated are accounted for as equity method investments. SEC Staff Announcement: Accounting for Limited Partnership Investments (codified in ASC 323-30-S99-1) guidance requires the use of the equity method unless the investor's interest "is so minor that the limited partner may have virtually no influence over partnership operating and financial policies." The SEC staff's position is that investments in limited partnerships of greater than 3% to 5% are considered more than minor and, therefore, should be accounted for using the equity method or fair value option. Investments accounted for using the equity method may be reported on a lag up to three months if financial statements of the investee are not available in sufficient time for the investor to apply the equity method as of the current reporting date. The determination of whether an investee's results are recorded on a lag is made on an investment-by-investment basis. This investment in joint venture is further described in Note of 6 these consolidated financial statements.

***Research and development costs***

Research and development costs, including acquired in-process research and development expenses for which there is no alternative future use, are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

***Stock-based compensation***

The Company accounts for share-based payment awards exchanged for services at the estimated grant date fair value of the award. Stock options issued under the Company's long-term incentive plans are granted with an exercise price equal to no less than the market price of the Company's stock at the date of grant and expire up to ten years from the date of grant. These options generally vest over a one to five year period. The Company accounts for forfeited awards as they occur.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

*Expected Term* - The expected term of options represents the period that the Company's stock-based awards are expected to be outstanding based on the simplified method, which is the half-life from vesting to the end of its contractual term.

*Expected Volatility* - The Company computes stock price volatility over expected terms based on its historical common stock trading prices.

*Risk-Free Interest Rate* - The Company bases the risk-free interest rate on the implied yield available on U.S. Treasury zero-coupon issues with an equivalent remaining term.

*Expected Dividend* - The Company has never declared or paid any cash dividends on its common shares and does not plan to pay cash dividends in the foreseeable future, and, therefore, uses an expected dividend yield of zero in its valuation models.

***Income taxes***

Income taxes are recorded in accordance with ASC 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

***Net loss per share***

Net loss per share is computed by dividing net loss by the weighted average number of common stock outstanding during the period. Since the Company had a net loss in the periods presented, basic and diluted net loss per common share are the same. The following were excluded from the computation of diluted shares outstanding due to the losses for each period presented, as they would have had an anti-dilutive impact on the Company's net loss:

| | As of December 31, | |
|---|---|---|
| **Potentially dilutive securities** | **2021** | **2020** |
| Warrants | 10,070,764 | 1,235,266 |
| Options | 1,321,212 | 689,212 |
| Non-vested restricted stock awards | 2,801 | 9,882 |
| Total | 11,394,777 | 1,934,360 |

***Recent accounting pronouncements***

In December 2019, FASB issued ASU No. 2019-12, *"Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company adopted ASU 2019-12 effective January 1, 2021, and the adoption did not have a material impact on its consolidated financial statements.

**Note 3—License agreements**

The following summarizes the Company's research and development expenses for licenses acquired during the years ended December 31, 2021 and 2020:

| | For the years ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| The George Washington University | $ 99,782 | $ 169,012 |
| Chelexa Biosciences, Inc. and the University of Cincinnati | - | 10,000 |
| University of Maryland and Isoprene Pharmaceuticals, Inc. | 15,000 | 35,000 |
| North Carolina State University | 30,000 | - |
| Virginia Commonwealth University | 30,000 | 365,000 |
| University of Cincinnati | - | 26,550 |
| U.S. Army Medical Research and Development Command | - | 2,000 |
| | **$ 174,782** | **$ 607,562** |

**The George Washington University**

On February 1, 2020 ("GW the Effective Date"), the Company entered into a patent license agreement with GW pursuant to which GW granted the Company a license to certain patent rights to, among other things, make, use, offer and sell certain licensed products throughout the world with respect to HT-001. On the GW Effective Date, the Company paid GW $2,500, and on February 27, 2020, the Company paid GW $10,000 as a license initiation fee. Until the first commercial sale of HT-001, the Company shall pay (i) $75,000 per year for the development and commercialization of HT-001, (ii) $2,000 for license maintenance fees on the first anniversary of the GW Effective Date and (iii) $5,000 for license maintenance fees commencing on the second anniversary of the GW Effective Date and thereafter. Furthermore, the Company shall be required to pay GW a sublicense fee equal to a certain percentage of the sum of payments plus the fair market value of all other consideration of any kind received by the Company from sublicensees during each quarter as follows: a 40% sublicense fee until the first anniversary of the GW Effective Date, a 30% sublicense fee until the third anniversary of the GW Effective Date and a 20% sublicense fee after the third anniversary of the GW Effective Date; provided, however, such sublicense fee shall exclude certain fees paid to the Company such as certain royalties, equity investments, loan proceeds and sponsored research funding. The Company shall also pay GW milestone payments of up to an aggregate of $90,000 and sales-based royalties at a low single digit percentage, subject to certain minimum royalty requirements.

Effective as of June 1, 2019, the Company and GW entered into a sponsored research agreement (the "Sponsored Research Agreement"), as amended on July 29, 2019, May 29, 2020 and September 7, 2021, with respect to the exploration of the potential use of HT-001 for topical and/or systemic therapy to counter the dermatological related side-effects of Erlotinib therapy in cancer patients. The Sponsored Research Agreement shall terminate on May 31, 2022 unless terminated earlier pursuant to the terms of the agreement.

On August 7, 2020 (the "GW Second Effective Date"), the Company entered into a second Patent License Agreement (the "GW Second Patent License Agreement") with GW pursuant to which GW granted the Company an exclusive, worldwide, royalty bearing license to certain intellectual property that can be used to develop a breath based diagnostic device. The GW Second Patent License Agreement permits the Company to make, have made, use, import, offer for sale and sell Licensed Products (as defined in the GW Second Patent License Agreement) in the field of virus sensing and detection. The term of the GW Second Patent License Agreement shall continue until the later of: (a) the expiration or abandonment of the last patent to expire or become abandoned of the Patent Rights (as defined in the GW Second Patent License Agreement); or (b) ten years after the first Sale (as defined in the GW Second Patent License Agreement) of the first Licensed Product if no patent has issued from the Patent Rights, unless terminated earlier pursuant to the terms of the agreement. Pursuant to the GW Second Patent License Agreement, the Company shall pay GW: (i) an upfront license initiation fee, (ii) annual maintenance fees commencing on the first anniversary of the GW Second Effective Date, (iii) milestone payments ranging from the low to mid five figures, (iv) running royalty payments at a middle single digit percentage of Net Sales (as defined in the GW Second Patent License Agreement), (iv) quarterly minimum payments ranging from the low four figures for the first four quarters after the first sale to low five figures commencing three years after the first sale and (v) an annual diligence fee of high five figures. In addition, the Company has agreed to reimburse GW for certain past and future patent filing and prosecution costs.

On September 17, 2020, the Company entered into a second Sponsored Research Agreement (the "Second Agreement") with GW effective as of September 1, 2020 (the "Second Agreement Effective Date"). The Second Agreement relates to the development of a diagnostic device for the detection of SARS-CoV-2 via a mobile device as an aid in the diagnosis of the COVID-19 infection. The Second Agreement was terminated on February 26, 2021.

During the year ended December 31, 2020, the Company paid $10,000 for license initiation fee, $10,000 for option exercise fee and approximately $15,000 patent related expense. The Company also recorded an expense of approximately $134,000 related with warrants granted to GW pursuant to the GW Patent License Agreement and GW Second Patent License Agreement.

During the year ended December 31, 2021, the Company recorded an expense of approximately $0.1 million for related to warrants granted to GW pursuant to the GW Patent License Agreement and the Second GW Patent License Agreement.

**Chelexa Biosciences, Inc. and the University of Cincinnati**

On May 14, 2020, the Company entered into an Assignment and Assumption Agreement (the "Assignment Agreement") with Chelexa Biosciences, Inc. ("Chelexa") pursuant to which Chelexa assigned to the Company its rights and obligations in and liabilities under its license agreement with the University of Cincinnati dated February 27, 2013 (as amended, the "University of Cincinnati License Agreement"). In consideration for the assignment, the Company agreed to forgive all amounts due to it by Chelexa and to pay to Chelexa certain royalty payments.

In connection with the Assignment Agreement, on May 14, 2020, the Company entered into a novation agreement (the "Novation Agreement") with Chelexa and the University of Cincinnati pursuant to which the parties agreed that the Company would be substituted in place of Chelexa with respect to the rights and obligations of Chelexa set forth in the University of Cincinnati License Agreement.

In connection with the Assignment Agreement, on May 14, 2020, the Company entered into a royalty agreement (the "Royalty Agreement") with Chelexa pursuant to which the Company shall pay Chelexa sales-based royalties at percentages which range from mid to high single digits, with high sales volumes being subject to lower royalty rates and total milestone payments of $3.5 million.

Pursuant to the University of Cincinnati License Agreement, the Company was granted an exclusive license to make, use, have made, import, offer for sale, and sell products based upon or involving the use of (i) topical compositions comprising a zinc chelator and gentamicin and (ii) zinc chelators to inhibit biofilm formation (the "BioLexa Platform" or "BioLexa"). In addition, the University of Cincinnati granted the Company the right to issue exclusive and nonexclusive sublicenses (with the right to further sublicense to third parties) to make, use, have made, import, offer for sale, and sell products based upon the BioLexa Platform. The term of such agreement will expire on the later of April 16, 2034 and the last to expire patent in the patent rights granted to the Company (the "Term"). The Company shall, in its sole discretion, have the first right of refusal to renew the Term. The Company is subject to total milestone payments of $6,000, royalty payments, annual license maintenance fees, and has agreed to pay the University of Cincinnati for certain out-of-pocket expenses including, but not limited to, payments for patent prosecution.

During the year ended December 31, 2021, the Company paid $2,500 for the annual license maintenance fee and $5,000 for the yearly minimum annual royalty fee.

During the year ended December 31, 2020, the Company paid a total of $2,500 for the annual license maintenance fee, $5,000 for the yearly minimum annual royalty fee and approximately $2,000 for patent expense reimbursement. As of December 31, 2020, the Company accrued a $7,500 for an upfront license payment. The payment was made in 2021.

**University of Maryland and Isoprene Pharmaceuticals, Inc.**

On July 30, 2020 (the "Isoprene Effective Date"), the Company entered into a Sublicense Agreement (the "Isoprene Sublicense Agreement") with Isoprene Pharmaceuticals, Inc. ("Isoprene"). Pursuant to the Isoprene Sublicense Agreement, Isoprene granted the Company an exclusive sublicense to certain intellectual property (i) to make, have made, use, sell, offer to sell and import certain licensed products, (ii) in connection therewith, to use certain inventions and licensed materials and (iii) to practice the Patent Rights (as defined in the Isoprene Sublicense Agreement) for the treatment of dermatological conditions or diseases. The Isoprene Sublicense Agreement will continue on a country-by-country basis until the expiration of the last to expire of the Patent Rights in such country, unless earlier terminated pursuant to the Isoprene Sublicense Agreement (the "Isoprene Term"). Pursuant to the Isoprene Sublicense Agreement, the Company shall pay Isoprene, among other things, (i) a license fee, (ii) a royalty rate at a middle single digit percentage, (iii) milestone payments of up to $1,375,000 and (iv) revenue interest at a low single digit percentage based on the net revenue of covered products sold by Isoprene during the Isoprene Term.

On December 2, 2020, the Company entered into an option agreement (the "Option Agreement") with Isoprene, pursuant to which the Company had an exclusive option, until June 2, 2021, to negotiate an exclusive, royalty-bearing and limited term license with respect to certain previously sublicensed intellectual property for the diagnosis and treatment of inflammatory bowel diseases, including Crohn's disease and ulcerative colitis, which option was exercised on July 2, 2021.This Option Agreement is based upon and expands the fields of use in which the Company can license certain Isoprene intellectual property that is the subject of the Company's existing Sublicense Agreement, dated July 30, 2020, with Isoprene, and the Master License Agreement, dated July 8, 2020, by and between Isoprene and the University of Maryland, Baltimore.

During the year ended December 31, 2020, the Company paid $10,000 for the license fee and $20,000 for the option exercise fee. As of December 31, 2020, the Company accrued a $5,000 for an upfront license payment.

During the year ended December 31, 2021, the Company paid $15,000 for the license fee.

**North Carolina State University**

On February 25, 2021 (the "Effective Date"), the Company entered into a License Agreement (the "License Agreement") with North Carolina State University ("NC State") pursuant to which NC State granted the Company an exclusive, worldwide, royalty bearing license to certain intellectual property to, among other things, discover, develop, make, have made, use and sell certain licensed products and sell, use and practice certain licensed services with respect to cancer and anaphylaxis. The License Agreement commenced on the Effective Date and continues until the later of (i) the date of expiration of the last to expire patents rights licensed pursuant to such agreement, including any renewals or extensions thereof and (ii) expiration of any market exclusivity period granted for a licensed product by the applicable regulatory agency.

During the year ended December 31, 2021, the Company paid $30,000 for the license fee.

**Virginia Commonwealth University**

On May 18, 2020 (the "VCU Effective Date"), the Company entered into an Exclusive License Agreement (the "VCU License Agreement") with the Virginia Commonwealth University Intellectual Property Foundation ("VCU"). Pursuant to the VCU License Agreement, VCU granted the Company an exclusive, royalty bearing license to a novel peptide developed by researchers at VCU that may be used to slow the transmission of SARS-CoV-2 (the "VCU Licensed Patent") and a non-exclusive royalty bearing, worldwide license with respect to the Licensed Technical Information Patents (as defined in the VCU License Agreement) to make, have made, use, offer to sell, sell and import the Licensed Products (as defined in the VCU License Agreement) and perform the Licensed Services (as defined in the VCU License Agreement). The VCU License Agreement commenced on the VCU Effective Date and shall continue until the expiration of the last to expire VCU Licensed Patent unless terminated earlier pursuant to the terms of the agreement. Pursuant to the VCU License Agreement, the Company shall pay VCU: (i) an upfront license issue fee, (ii) running royalty payments at a low single digit percentage of Net Sales (as defined in the VCU License Agreement), (iii) annual maintenance fees commencing on the first anniversary of the VCU Effective Date, (iv) annual minimum payments ranging from the mid five figures to low six figures commencing on the second anniversary of the VCU Effective Date and (v) milestone payments ranging from the mid five figures to low six figures. In addition, the Company has agreed to reimburse VCU for certain patent filing and prosecution costs.

On June 29, 2020, the Company entered into a Sponsored Project Agreement (the "VCU Sponsored Project Agreement") with VCU for the development of a potential COVID-19 treatment using the license to a novel peptide granted to the Company by VCU. The VCU Sponsored Project Agreement was amended on April 28, 2021 to extend the period of research and to add an additional scope of investigation to include the variants of SARS-CoV-2.

In May 2020, the Company paid the signing fee of $50,000 upon execution of the VCU License Agreement.

During the year ended December 31, 2021, the Company paid $30,000 for annual maintenance fees.

As of December 31, 2021 and 2020, the Company accrued $285,000 for five years of annual minimum payments and $30,000 for annual maintenance fees.

**The University of Cincinnati**

On May 18, 2018, the Company entered into an exclusive license agreement with the University of Cincinnati for a patented, novel genetic marker for food allergies. The genetic marker licensed by the Company from the University of Cincinnati may be used to (i) identify at risk infants in predicting food allergies, including peanut and milk allergies, (ii) identify a person's predisposition to an allergic reaction, thereby avoiding such reaction and (iii) determine an individual's propensity to develop atopic dermatitis, such as eczema. Pursuant to the terms of the exclusive license agreement, the Company paid the University of Cincinnati a minimum annual royalty fee of $5,000 and agreed to pay the University of Cincinnati an annual license fee of $5,000 initially due and payable within 30 days of the one year anniversary of the exclusive license agreement and every year thereafter and milestone payments of up to $120,000. The exclusive license agreement was terminated by the Company on October 22, 2021.

During the year ended December 31, 2021, the Company paid $5,000 for the annual license maintenance fee and $5,000 for the yearly minimum annual royalty fee.

During the year ended December 31, 2020, the Company paid a total of $5,000 for the annual license maintenance fee, $5,000 for the yearly minimum annual royalty. As of December 31, 2020, the Company accrued a $10,500 for an upfront license payment. The payment was made in 2021.

**U.S. Army Medical Research and Development Command**

On December 11, 2020, the Company entered into a commercial evaluation license agreement with U.S. Army Medical Research and Development Command ("USAMRDC"). This agreement was amended on January 12, 2021 to clarify that the license entered into is with Walter Reed Army Institute of Research, a subsidiary of USAMRDC.

As of December 31, 2020, the Company accrued a $2,000 for an upfront license payment. The payment was made in January 2021.

**Note 4—Note Receivable**

Pursuant to Isoprene Sublicense Agreement dated July 30, 2020, the Company made an investment of $50,000 in Isoprene in the form of a convertible promissory note (the "Isoprene Note") on September 10, 2020. The Isoprene Note matures on September 10, 2022 and accrues interest at a rate equal to the lower of: (i) the highest lawful rate permitted under applicable law and (ii) 6% per annum. The Isoprene Note may not be prepaid without the prior written consent of the Company. In the event a Qualified Financing (as defined below) occurs before the Isoprene Note is repaid in full or the conversion of such note pursuant to a Change of Control (as defined in the Isoprene Note) transaction, the Isoprene Note may be converted into such number of convertible preferred stock issued in the Qualified Financing equal to the balance of such note divided by the Capped Conversion Price (as defined below). "Qualified Financing" means the first sale of Isoprene's convertible preferred in a private financing that results in gross proceeds of at least $5 million. "Capped Conversion Price" means the lesser of (i) the per share or unit price in the Qualified Financing and (ii) an amount determined by dividing (A) $15 million by (B) the fully diluted capitalization Isoprene immediately prior to the conversion of the Isoprene Note. In the event a Change of Control occurs before the Isoprene Note is repaid in full or the conversion of such note pursuant to a Qualified Financing, the Isoprene Note may be converted into such number of shares of Isoprene's common stock equal to the quotient obtained by dividing (i) the balance of the Isoprene Note by (ii) two times the fair market value of a share of Isoprene common stock as set for in the acquisition agreement pertaining to such Change of Control.

**Note 5—Investments in Marketable Securities**

The realized gain or loss, unrealized gain or loss, and dividend income related to marketable securities for the years ended December 31, 2021 and 2020, which are recorded as a component of other income (expenses) on the consolidated statements of operations, are as follows:

| | For the years ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Unrealized gain | $ (176,974) | $ 50,553 |
| Realized loss | (41,808) | (1,177) |
| Dividend income | 66,101 | 31,152 |
| Interest income | - | 8 |
| | $ (152,683) | $ 80,536 |

**Note 6—Fair Value of Financial Assets and Liabilities**

The following table presents the Company's assets and liabilities that are measured at fair value at December 31, 2021 and 2020:

| | Fair value measured at December 31, 2021 | | | |
|---|---|---|---|---|
| | Total at December 31, 2021 | Quoted prices in active markets (Level 1) | Significant other observable inputs (Level 2) | Significant unobservable inputs (Level 3) |
| Assets | | | | |
| Marketable securities - mutual funds | $ 1,892,837 | $ 1,892,837 | $ - | $ - |
| Investment in joint venture | $ 410,000 | $ - | $ - | $ 410,000 |
| Note receivable - current | $ 50,000 | $ - | $ - | $ 50,000 |

| | Fair value measured at December 31, 2020 | | | |
|---|---|---|---|---|
| | Total at December 31, 2020 | Quoted prices in active markets (Level 1) | Significant other observable inputs (Level 2) | Significant unobservable inputs (Level 3) |
| Assets | | | | |
| Marketable securities - mutual funds | $ 2,063,236 | $ 2,063,236 | $ - | $ - |
| Investment in joint venture | $ 410,000 | - | - | $ 410,000 |
| Note receivable | $ 50,000 | - | - | $ 50,000 |

***Investment in joint venture***

The Company has elected to measure the investment in joint venture using the fair value option at each reporting date. Under the fair value option, bifurcation of an embedded derivative is not necessary, and all related gains and losses on the host contract and derivative due to change in the fair value will be reflected in interest income and other, net in the consolidated statements of operations.

The value at which the Company's investment in joint venture is carried on its books is adjusted to estimated fair value at the end of each quarter, taking into account general economic and stock market conditions and those characteristics specific to the underlying investments.

*Investment in HaloVax*

On March 23, 2020, the Company entered into a Development and Royalty Agreement (the "Development and Royalty Agreement") with Voltron Therapeutics, Inc. ("Voltron") to form a joint venture entity named HaloVax, LLC ("HaloVax") to jointly develop potential product candidates for the prevention of COVID-19 based upon certain technology that had been exclusively licensed by Voltron from The General Hospital Corporation (d/b/a Massachusetts General Hospital). Pursuant to the Development and Royalty Agreement, the Company is entitled to receive sales-based royalties. In addition, pursuant to the terms of the Development and Royalty Agreement, on March 23, 2020, the Company and HaloVax entered into a Membership Interest Purchase Agreement pursuant to which the Company purchased 5% of HaloVax's outstanding membership interests for $250,000 on March 27, 2020 (the "Initial Closing Date") and had the option to purchase up to an additional 25% of HaloVax's membership interests (for $3,000,000 (inclusive of the $250,000)), which option expired 30 days after the Initial Closing Date. On May 28, 2020, the Company entered into a membership interest purchase agreement to purchase 1% of HaloVax's outstanding membership interest for a purchase price of $100,000. No change in fair value occurred during the year ended December 31, 2021 and 2020.

*Investment in Zylö*

In connection with the Company's March 2020 underwritten public offering of shares of its common stock, on May 4, 2020, the Company purchased 120,000 shares of Zylö's Class B common stock for $60,000. No change in fair value occurred during the year ended December 31, 2021 and 2020. On December 8, 2021, the Company entered into a third amendment (the "Zylö Amendment") to the Exclusive Sublicense Agreement with Zylö originally dated August 19, 2019 pursuant to which the Company licensed its novel cannabinoid therapeutic, HT-005 for lupus patients, back to Zylö. Pursuant to the Zylö Amendment, on December 6, 2021 Zylö issued the Company 100,000 shares of its Class B common stock. In addition, pursuant to the Zylö Amendment, within 90 days following a sale by Zylö of all of its assets and rights related to HT-005 to a third party (a "Sale"), Zylö shall pay the Company a low single digit percent of the net proceeds received by it attributable to HT-005 in the United States and Canada and their respective territories (collectively, the "Territory") for the purposes of therapeutic uses related to lupus in humans (the "Field"). After the Sale, any and all rights of the Company pursuant to the Exclusive Sublicense Agreement, including all amendments thereto, shall terminate. Furthermore, pursuant to the Zylö Amendment, following the date of the first commercial sale of HT-005 in the Territory, in the Field, Zylö shall pay the Company (i) a low single digit percent of the Net Sales (as defined in the Exclusive Sublicense Agreement) of HT-005 in the event HT-005 is sold in the Territory and (ii) a low double digit percent of any royalty that Zylö receives through the sublicense to a third party based on Net Sales of HT-005 in the Territory which payments shall continue in each country in the Territory until expiration of the last-to-expire Valid Claim (as defined in the Exclusive Sublicense Agreement).

***Note receivable***

As of December 31, 2021, the fair value of the Isoprene Note was measured at $50,000, taking into consideration cost of the investment, market participant inputs, market conditions, liquidity, operating results and other qualitative and quantitative factors. No change in fair value was recorded during the year ended December 31, 2021.

**Note 7—Stockholders' Equity**

**Preferred Stock**

The Company is authorized to issue up to 10,000,000 shares of preferred stock. This preferred stock may be issued in one or more series, and shall have such designations, preferences and relative, participating, optional or other special rights and qualifications, limitations or restrictions thereof as shall be determined at the time of issuance by the Company's board of directors without further action by the Company's shareholders. As of December 31, 2021, 5,000,000 shares of the Company's preferred stock has been designated as Series A Convertible Preferred Stock.

The shares of Series A Convertible Preferred Stock are not mandatorily redeemable and do not embody an unconditional obligation to settle in a variable number of equity shares. As such, the shares of Series A Convertible Preferred Stock are classified as permanent equity on the balance sheets. The holders' contingent redemption right in the event of certain deemed liquidation events does not preclude permanent equity classification. Further, the shares of Series A Convertible Preferred Stock are considered an equity-like host for purposes of assessing embedded derivative features for potential bifurcation. The embedded conversion feature is considered to be clearly and closely related to the associated convertible preferred stock host instrument and therefore was not bifurcated from the equity host.

**Common Shares**

On February 5, 2020, the Company issued 12,500 shares of common stock upon exercise of warrants issued to an investor on January 19, 2018, which resulted in gross proceeds of $12,500.

On March 6, 2020, the Company issued 25,000 shares of common stock upon exercise of warrants issued to an investor on December 14, 2017, which resulted in gross proceeds of $25,000.

On May 18, 2020, the Company issued 6,250 shares of common stock upon exercise of warrants issued to an investor on February 2, 2018, which resulted in gross proceeds of $6,250.

On June 3, 2020, the Company issued 12,500 shares of common stock upon exercise of warrants issued to an investor on November 20, 2017, which resulted in gross proceeds of $12,500.

During the year ended December 31, 2020, the Company issued an aggregate of 9,984 shares of the Company's common stock to members of the Company's Board for services rendered.

Public Offering of Securities

On March 24, 2020 (the "UA Effective Date"), the Company entered into an underwriting agreement with Laidlaw & Company (UK) Ltd. ("Laidlaw"), the representative of the underwriters, relating to a best efforts underwritten public offering of 1,449,275 shares (the "Shares") of the Company's common stock at a public offering price of $3.45 per Share. The Company received net proceeds of approximately $4.2 million, after deducting the underwriting discount and offering expenses.

In connection with the offering, on March 26, 2020, the Company issued Laidlaw warrants to purchase up to 72,464 shares of the Company's common stock. The warrants are exercisable for a period of five years from the UA Effective Date at a price per share equal to $4.14, subject to adjustment, and may be exercised on a cashless basis. The Company reimbursed Laidlaw for certain of its out-of-pocket expenses incurred in connection with the offering.

On May 21, 2020, the Company entered into an underwriting agreement with The Benchmark Company, LLC ("Benchmark"), as representative of the several underwriters, relating to the public offering of 1,818,182 shares of the Company's common stock at a price to the public of $2.75 per share. The Company received net proceeds of approximately $4.5 million, after deducting the underwriting discount and offering expenses.

In connection with the offering, on May 27, 2020 (the "Benchmark Issue Date"), the Company issued Benchmark warrants to purchase up to 90,909 shares of the Company's common stock. The warrants are exercisable for a period of five years commencing six months from the Benchmark Issue Date at a price per share equal to $2.75, subject to adjustment, and may be exercised on a cashless basis.

Securities Purchase Agreements

On January 5, 2021, the Company entered into a securities purchase agreement with certain accredited investors pursuant to which the Company offered and sold to the investors an aggregate of 2,475,248 shares of its common stock and warrants to purchase up to 1,237,624 shares of common stock in a private placement for aggregate net proceeds to the Company of $4.6 million, after deducting estimated offering expenses payable by the Company. The combined purchase price for each share of common stock and accompanying warrant to purchase one half of a share of common stock was $2.02. The closing of the offering occurred on January 7, 2021. Each warrant is exercisable for a period of five years from the issuance date at an exercise price of $2.25 per share, subject to adjustment, and may be exercised on a cashless basis. In addition, pursuant to the terms of the offering, the Company issued The Benchmark Company, LLC ("Benchmark") warrants to purchase up to 185,644 shares of the Company's common stock. Benchmark's warrants are exercisable for a period of five years from the closing date of the offering at an exercise price of $2.25 per share, subject to adjustment, and may be exercised on a cashless basis.

On March 8, 2021, the Company entered into a securities purchase agreement with certain institutional and accredited investors pursuant to which it offered and sold to the investors 6,826,962 shares of common stock, pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 767,975 shares of common stock and warrants (the "Common Stock Warrants") to purchase up to 7,594,937 shares of common stock in a private placement for aggregate net proceeds to the Company of $13.5 million, after deducting estimated offering expenses payable by the Company. The combined purchase price for each share of common stock and accompanying warrant was $1.975. The closing of the offering occurred on March 10, 2021. Each Common Stock Warrant is exercisable for a period of three years from the issuance date at an exercise price of $1.86 per share, subject to adjustment, and may be exercised on a cashless basis. Each Pre-Funded Warrant is exercisable until exercised in full at an exercise price of $0.001 per share and may be exercised by means of a cashless exercise. In addition, pursuant to the terms of the offering, the Company issued H.C. Wainwright & Co., LLC warrants ("Wainwright Warrants") to purchase up to 379,747 shares of the Company's common stock. The Wainwright Warrants are exercisable for a period of three years from the issuance date at an exercise price of $2.4688 per share, subject to adjustment, and may be exercised by on a cashless basis.

**2018 Equity Incentive Plan**

The compensation committee of the board of directors increased the number of shares reserved pursuant to the Company's 2018 Equity Incentive Plan ("2018 Plan") by 671,926 shares effective as of January 1, 2021, such that as of January 1, 2021, the Company had an aggregate of 1,671,926 shares of common stock reserved for issuance pursuant to the 2018 Plan. On June 24, 2021, at the annual shareholder meeting, shareholders of the Company approved an amendment to the 2018 Plan to further increase the number of shares reserved for issuance thereunder from 1,671,926 shares to 3,671,926 shares.

**Restricted Stock Awards**

A summary of the Company's restricted stock awards granted under the 2018 Plan during the years ended December 31, 2021 and 2020 is as follows:

| | Number of Restricted Stock Awards | Weighted Average Grant Day Fair Value |
|---|---|---|
| Nonvested at December 31, 2019 | 13,200 | $ 0.25 |
| Granted | 6,666 | 3.00 |
| Vested | (9,984) | 0.49 |
| Nonvested at December 31, 2020 | 9,882 | $ 1.86 |
| Granted | 100,000 | 1.24 |
| Vested | (107,081) | 1.23 |
| Nonvested at December 31, 2021 | 2,801 | $ 3.00 |

As of December 31, 2021, there is approximately $2,000 of unrecognized stock-based compensation expense related to restricted stock awards. The weighted average remaining contractual terms of unvested restricted stock awards is approximately 0.63 years at December 31, 2021.

**Stock Options**

During the year ended December 31, 2021, pursuant to and subject to the available number of shares reserved under the 2018 Plan, the Company issued an aggregate of 632,000 options to the Company's directors. The aggregate grant date fair value of these options was approximately $1.1 million.

During the year ended December 31, 2020, pursuant to and subject to the available number of shares reserved under the 2018 Plan, the Company issued an aggregate of 200,000 options to the Company's directors. The aggregate grant date fair value of these options was approximately $0.5 million. The Company also issued 49,212 options to purchase common stock of the Company to a third party for consulting services. The aggregate grant date fair value of these options was approximately $0.1 million.

The fair value of options granted in 2021 and 2020 was estimated using the following assumptions:

| | For the years ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Exercise price | $ 2.11 | $ 2.54-3.05 |
| Term (years) | 10.0 | 9.52-9.56 |
| Expected stock price volatility | 119.2% | 114.2 % - 114.5% |
| Risk-free rate of interest | 0.42% | 0.3% |

A summary of option activity under the Company's stock option plan for the years ended December 31, 2021 and 2020 is presented below:

| | Number of Shares | Weighted Average Exercise Price | Total Intrinsic Value | Weighted Average Remaining Contractual Life (in years) |
|---|---|---|---|---|
| Outstanding as of December 31, 2019 | 525,000 | $ 5.32 | $ 457,250 | 9.4 |
| Employee options issued | 200,000 | 3.05 | - | 8.8 |
| Non - employee options issued | 49,212 | 2.54 | - | 9.5 |
| Forfeited | (85,000) | - | - | - |
| Outstanding as of December 31, 2020 | 689,212 | $ 4.52 | $ - | 8.8 |
| Employee options issued | 632,000 | 2.11 | - | 9.3 |
| Outstanding as of December 31, 2021 | 1,321,212 | $ 3.37 | $ - | 8.6 |
| Options vested and exercisable as of December 31, 2021 | 1,321,212 | $ 3.37 | $ - | 8.6 |

Stock-based compensation associated with the amortization of stock option expense was approximately $1.1 million and $0.6 for the year ended December 31, 2021 and 2020, respectively. All stock compensation associated with the amortization of employee stock option expense was recorded as a component of compensation and related expense in the statement of operations. All stock compensation associated with the amortization of nonemployee stock option expense was recorded as a component of professional fees in the statement of operations.

Estimated future stock-based compensation expense relating to unvested stock options is approximately $0.

**Stock Based Compensation**

Stock-based compensation expense for the years ended December 31, 2021 and 2020 was as follows:

| | For the years ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Employee stock option awards | $ 1,092,429 | $ 487,963 |
| Non-employee stock option awards | - | 100,104 |
| Employee restricted stock awards | 6,611 | 15,510 |
| Non-employee restricted stock awards | 124,000 | - |
| Non-employee stock warrant awards | 99,782 | 134,169 |
| | **$ 1,322,821** | **$ 737,746** |

Employee and director related stock-based compensation was included in compensation and related expenses, and non-employee related stock-based compensation was included in professional fees and research and development related with licenses acquisition in the consolidated statements of operations and comprehensive loss.

**Warrants**

Pursuant to the Patent License Agreement between the Company and GW dated February 1, 2020, on February 27, 2020 (the "February Warrant Date of Issuance"), the Company issued GW ten year warrants (the "February Warrants") to purchase up to 22,988 shares of the Company's common stock at an exercise price of $4.35 per share. The February Warrants vest as follows: 20% on the February Warrant Date of Issuance and the balance, or 80% of the February Warrants, vest in four equal annual installments of 20% on each anniversary of the February Warrant Date of Issuance.

Pursuant to the GW Patent License Agreement, on August 10, 2020 (the "August Warrant Date of Issuance"), the Company issued GW ten year warrants (the "August Warrants") to purchase up to 72,463 shares of the Company's common stock at an exercise price of $2.76 per share. The August Warrants vest as follows: 20% on the August Warrant Date of Issuance and the balance, or 80% of the August Warrants, shall vest in four equal annual installments of 20% on each anniversary of the August Warrant Date of Issuance.

In connection with the public offering of securities discussed above, the Company granted to Laidlaw and Benchmark warrants to purchase up to 72,464 and 90,909 shares of the Company's common stock, respectively.

A summary of warrant activity for the years ended December 31, 2021 and 2020 is presented below:

| | Number of Warrants | Weighted Average Exercise Price | Total Intrinsic Value | Weighted Average Remaining Contractual Life (in years) |
|---|---|---|---|---|
| Outstanding as of December 31, 2019 | 1,032,692 | $ 2.91 | $ 3,725,745 | 4.2 |
| Issued | 258,824 | 3.28 | - | 4.9 |
| Exercised | (56,250) | 1.00 | - | - |
| Outstanding as of December 31, 2020 | 1,235,266 | $ 3.07 | $ 696,334 | 3.4 |
| Issued | 10,165,927 | 1.80 | - | 2.3 |
| Expired | (203,709) | 8.00 | - | - |
| Exercised | (1,126,720) | 0.32 | - | - |
| Outstanding as of December 31, 2021 | 10,070,764 | $ 1.99 | $ - | 2.3 |
| Warrants exercisable as of December 31, 2021 | 10,013,495 | $ 1.99 | $ - | 2.5 |

The Company has determined that the warrants should be accounted as a component of stockholders' equity.

**Note 8—Commitments and contingencies**

***Office lease***

The Company leases office space for approximately $4,500 a month. Rent expense for the years ended December 31, 2021 and 2020 was approximately $47,000 and $25,000, respectively. The Company is not a party to a lease that is in excess of 12 months.

***Litigation***

The Company is not a party to any material legal proceedings and is not aware of any pending or threatened claims. From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities.

**Note 9—Income taxes**

The table below presents the components of the provision for taxes:

The Company's provision is driven by refundable tax credits generated by its subsidiary in Australia.

| | As of December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Current | | |
| U.S. Federal | $ - | $ - |
| U.S. State | - | - |
| US. Foreign | (548,660) | - |
| Total current provision | (548,660) | - |
| Deferred | | |
| U.S. Federal | - | - |
| U.S. State | - | - |
| US. Foreign | - | - |
| Total deferred benefit | - | - |
| Change in valuation allowance | (548,660) | - |
| Total provision for income taxes | $ - | $ - |

At December 31, 2021 and 2020, the tax effects of the temporary differences and carryforwards that give rise to deferred tax assets consist of the following:

| | As of December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Net operating loss carryforwards | $ 6,752,718 | $ 3,336,268 |
| Research and development credits | 444,866 | - |
| Equity based compensation | 590,050 | 549,387 |
| Licenses acquired | 341,171 | 139,487 |
| Depreciation | 72 | 63 |
| Accruals and other temporary differences | 155,816 | - |
| Gross deferred tax assets | 8,284,693 | 4,025,205 |
| Depreciation | - | - |
| Accruals and other temporary differences | - | - |
| Less valuation allowance | (8,284,693) | (4,025,205) |
| Net deferred taxes | $ - | $ - |

A reconciliation of the statutory income tax rates and the Company's effective tax rate for the year ended December 31, 2021 and 2020 is as follows:

| | Years Ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Tax provision at statutory rate | 21.0% | 21.0% |
| State taxes, net of federal benefit | 8.2% | - |
| Permanent items | (1.8)% | (0.3)% |
| Credits | 6.7% | - |
| Equity compensation | (2.4)% | - |
| Rate changes | 2.4% | - |
| Foreign rate differential | - | - |
| Other | (0.3)% | - |
| Increase/(decrease) in valuation reserve | (30.0)% | (20.7)% |
| Total | **3.80%** | **-** |

The Company has determined, based upon available evidence, that it is more likely than not that the net deferred tax assets will not be realized and, accordingly, has provided a full valuation allowance against its net deferred tax assets.

As of December 31, 2021, the Company has net operating loss carryforwards of approximately $26.7 million and 22.4 million available to reduce future taxable income, if any, for Federal and state income tax purposes, respectively. Approximately $1.5 million of Federal net operating losses can be carried forward to future tax years and expire in 2037. The Federal net operating loss generated during the years ended after December 31, 2017 of approximately $25.2 million can be carried forward indefinitely; however, the deduction for net operating losses incurred in tax years beginning after December 31, 2017 is limited to 80% of annual taxable income.

As of December 31, 2021, the Company has research and development credits of approximately $0.4 million and $0 available to reduce future income taxes, if any, for Federal and state income tax purposes, respectively. The Federal credits expire if not utilized by 2041.

The utilization of the Company's net operating loss carryforwards and research tax credit carryovers could be subject to annual limitations under Section 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), and similar state tax provisions, due to ownership change limitations that may have occurred previously or that could occur in the future. These ownership changes limit the amount of net operating loss carryforwards and other deferred tax assets that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 and 383 of the Code, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percent points over a three-year period. The Company has not conducted an analysis of an ownership change under Section 382 of the Code. To the extent that a study is completed and an ownership change is deemed to occur, the Company's net operating losses and tax credits could be limited.

The following table summarizes the activity related to the Company's gross unrecognized tax benefits at the beginning and end of the years ended December 31, 2021 and December 31, 2020, respectively (in thousands):

| | As of December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Gross unrecognized tax benefits at the beginning of the year | $ - | $ - |
| Increases related to current year positions | - | - |
| Increases related to prior year positions | - | - |
| Decreases related to prior year positions | - | - |
| Expiration of unrecognized tax benefits | - | - |
| Gross unrecognized tax benefits at the end of the year | $ - | $ - |

At December 31, 2021 and 2020, the Company did not have any significant uncertain tax positions. The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2021 and 2020, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statement of operations. The Company does not anticipate a material change to unrecognized tax benefits in the next twelve months.

All of the Company's tax years will remain open for examination by the Federal and state tax authorities from the date of utilization of the net operating loss.

**Note 10—Risk and Uncertainties**

***COVID-19***

The outbreak of the novel Coronavirus (COVID-19) evolved into a global pandemic. The Coronavirus has spread to many regions of the world. The extent to which the Coronavirus impacts the Company's business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the Coronavirus, including variants, and the actions to contain the Coronavirus or treat its impact, among others.

As a result of the continuing spread of the Coronavirus, certain aspects of the Company's business operations have been delayed, and the Company may be subject to additional delays or interruptions. Specifically, as a result of the shelter-in-place orders and other mandated local travel restrictions, among other things, the research and development activities of certain of the Company's partners may be affected, which may result in delays to the Company's clinical trials, and the Company can provide no assurance as to when such trials, if delayed, will resume at this time or the revised timeline to complete trials once resumed.

Furthermore, site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. If the Coronavirus continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and the Company may be unable to conduct its clinical trials. Further, if the spread of the Coronavirus pandemic continues and the Company's operations are adversely impacted, the Company risks a delay, default and/or nonperformance under existing agreements which may increase its costs. These cost increases may not be fully recoverable or adequately covered by insurance.

Infections and deaths related to the pandemic may disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA review and/or approval with respect to, the Company's clinical trials. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of the Company's clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of the Company's product candidates.

The Company currently utilizes third parties to, among other things, manufacture raw materials. If any third-party party in the supply chain for materials used in the production of the Company's product candidates are adversely impacted by restrictions resulting from the Coronavirus outbreak, the Company's supply chain may be disrupted, limiting the Company's ability to manufacture its product candidates for its clinical trials and research and development.

The spread of the Coronavirus, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on the Company's business. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the Coronavirus could materially and adversely affect the Company's business and the value of its common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. The Company does not yet know the full extent of potential delays or impacts on its business, its clinical trials, its research programs, healthcare systems or the global economy as a whole. However, these effects could have a material impact on the Company's operations, and the Company will continue to monitor the situation closely.

***Nasdaq Delisting Notice***

On December 30, 2021, the Company received a written notice from the Nasdaq Stock Market LLC ("Nasdaq") informing the Company that the bid price of its common stock, par value $0.0001 per share, failed to comply with the $1.00 minimum bid price required for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), the Company was granted an initial 180 calendar day compliance period, or until June 28, 2022, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of the Company's common stock must meet or exceed $1.00 per share for at least 10 consecutive business days during the initial 180 calendar day compliance period. In the event the Company does not regain compliance by June 28, 2022, the Company may be eligible for an additional 180 calendar day grace period if the Company meets the continued listing standards for The Nasdaq Capital Market, with the exception of bid price, and the Company provides written notice to Nasdaq of its intention to cure the deficiency during the second compliance period.

**Note 11—Subsequent Events**

On February 2, 2022, the compensation committee of the Board of Directors of the Company approved an increase in the number of shares of common stock reserved for issuance under the 2018 Plan by 250,000 shares from 3,671,926 shares to 3,921,926 shares.

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS AND FINANCIAL DISCLOSURE

None.

## ITEM 9A. CONTROLS AND PROCEDURES

### Evaluation of Disclosure Controls

Our principal executive officer and principal financial officer, after evaluating the effectiveness of the Company's "disclosure controls and procedures" (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) as of December 31, 2021, the end of the period covered by this Annual Report on Form 10-K, have concluded that our disclosure controls and procedures were effective such that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

### Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with GAAP. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

As of December 31, 2021, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework - 2013. Based on this assessment, our management concluded that, as of December 31, 2021, our internal control over financial reporting was effective based on such criteria.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to the exemption provided to issuers that are not "large accelerated filers" nor "accelerated filers" under the Dodd-Frank Wall Street Reform and Consumer Protection Act.

### Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## ITEM 9B. OTHER INFORMATION

None.

## ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth the name, age and positions of our executive officers and directors.

| NAME | AGE | POSITION |
|---|---|---|
| Robb Knie | 53 | President, Chief Executive Officer and Director |
| David Briones | 45 | Chief Financial Officer |
| Stefanie Johns | 37 | Chief Scientific Officer |
| Wayne Linsley | 65 | Director |
| David B. Sarnoff | 54 | Director |
| Graig Springer | 42 | Director |

The business background and certain other information about our directors and executive officers is set forth below.

**Robb Knie**

Robb Knie has served as President and Chief Executive Officer and as a director of the Company since May 2017 and served as our principal financial and accounting officer from June 2018 until March 2019. Since October 15, 2020, Mr. Knie has served as the Chief Executive Officer, Chief Financial Officer and chairman of the board of directors of FoxWayne Enterprises Acquisition Corp. (Nasdaq: FOXW). Mr. Knie served as the President of Lifeline Industries Inc. since its inception in 1995. From 2002 to 2010 he was a Semiconductor Analyst for PAW Partners. From 1993 until 1995, Mr. Knie served as Northeast Regional Manager of American Express Financial Advisors. Mr. Knie has served as a board member for Nasdaq-listed companies. He has been featured on Bloomberg, The Wall Street Journal and Forbes Magazine as an Independent Equity Analyst. Mr. Knie has over 20 years of equity markets experience. Mr. Knie has been a member of the American Chemical Society, Institute of Electrical and Electronics Engineers, as well as The National Alliance for Youth Sports. We believe that Mr. Knie is qualified to serve as a director because of his business and leadership experience and experience as a board member of public companies in the healthcare industry.

**David Briones**

David Briones has served as Chief Financial Officer of the Company since March 2019 and has over nineteen years of public accounting and executive level experience. He consults with various public companies in financial reporting, internal control development and evaluation, budgeting and forecasting. Since September 2021, Mr. Briones has served as Chief Financial Officer, Treasurer and Secretary and a member of the board of directors of Larkspur Healthcare Acquisition Corp. (Nasdaq: LSPR), a special purpose acquisition corporation. Since October 2010, he has served as the managing member and founder of Brio Financial Group, LLC, a full-service financial consulting firm that brings experienced finance and accounting expertise to both public and private companies. Since 2010, Mr. Briones has served over 75 companies as well as numerous banks, hedge funds, venture capital funds and private equity firms. In addition, from May 2018 until its dissolution in April 2021, Mr. Briones served as Executive Chair of Zovis Pharmaceuticals, and from August 2013 to January 2020, Mr. Briones served as Chief Financial Officer of Petro River Oil Corp. (“PTRC”), an independent energy company focused on the exploration and development of conventional oil and gas assets. Mr. Briones also served as interim Chief Financial Officer of AdiTx Therapeutics, Inc. (Nasdaq: ADTX), a pre-clinical stage, life sciences company with a mission to prolong life and enhance life quality of transplanted patients from January 2018 to July 2020 (until the company’s initial public offering). From October 2017 to May 2018, Mr. Briones served as the Chief Financial Officer of Bitzumi, Inc., a Bitcoin exchange and marketplace. Prior to founding Brio Financial Group, LLC, Mr. Briones was an auditor with Bartolomei Pucciarelli, LLC in Lawrenceville, New Jersey and PricewaterhouseCoopers LLP in New York, New York. Since May 2020, Mr. Briones has served as a member of the board of directors of Unique Logistics International Inc (OTC Pink: UNQL). Mr. Briones received a bachelors of science degree in accounting from Fairfield University.

**Stefanie Johns**

Stefanie Johns has served as Chief Scientific Officer of the Company since September 2020. Prior to serving as our Chief Scientific Officer, from February 2019 to September 2020, Dr. Johns served as a member of the Company's Scientific Advisory Board, and from May 2020 to September 2020, she served as a consultant of the Company. Dr. Johns has worked in the biopharmaceutical and medical device industries for more than eight years, and has experience spanning drug, biologic, medical device, and in vitro diagnostic device products in U.S. and global markets. From January to September 2020, Dr. Johns served as Director, Regulatory Affairs of Enable Injections, Inc., and from January 2019 until January 2020, she served as Associate Director, Regulatory Affairs of Enable Injections, Inc., an investigational-stage company developing and manufacturing on-body subcutaneous infusion delivery systems. From December 2018 until August 2018, Dr. Johns served as Manager, Regulatory Strategy of Camargo Pharmaceutical Services, LLC ("Camargo") and from July 2016 until August 2018, she served as Scientific Regulator Specialist of Camargo, a company specializing in complex drug development programs. From June 2013 through June 2016, Dr. Johns served as Regulatory Affairs and Design Assurance Associate of Meridian Bioscience Inc., a producer and distributor of diagnostic test kits. In addition, Dr. Johns previously served as Program Manager, Xavier Health Initiatives for Xavier University and a Graduate Research Assistant for the University of Cincinnati. Dr. Johns received her bachelors of science degree in biological sciences from Wright State University and her Ph.D. in biochemistry from the University of Cincinnati College of Medicine.

**Wayne Linsley**

Wayne D. Linsley has served as a director of the Company since April 2020. Mr. Linsley has been in business management for over 40 years. He possesses a wide and varied skillset including sales and sales management, finance (for both public and private companies), accounting, audit support and financial reporting. He has a bachelor's in business administration from Siena College in Loudonville, NY. From 2009 to September 2021 he worked for a financial reporting firm that works with publicly traded companies. He has extensive knowledge of financial statements, MD&A, SEC Filings (10-K, 10-Q, 8-K, etc.) Edgar, etc. He often negotiated on behalf of clients in such areas as audit fees, transfer agents, Edgar companies, etc. He currently serves as an independent director for DatChat Inc. (Nasdaq: DATS), serving the chair of its audit committee, compensation committee and nominating and corporate governance committee, and Silo Pharma, Inc. (OTCQB: SILO). We believe Mr. Linsley is qualified to serve as a member of the Board because his business management experience.

**David B. Sarnoff**

David Sarnoff has served as a director of the Company since August 2018. Since June 2015, Mr. Sarnoff has served as the founder and Principal of Sarnoff Group, LLC, and since January 2019, he has served as the Director of Strategic Partnerships and Executive Leadership Coach at Loeb Leadership. In addition, since December 2021, Mr. Sarnoff has served as Adjunct Faculty at iCoach New York with respect to a professional coaching program. From October 2003 until June 2015, Mr. Sarnoff served as the co-founder and Principal of Morandi, Taub & Sarnoff LLC, an executive search firm, and from July 1998 until October 2003 he served as a Legal Recruiter for Schneider Legal Search, Inc. From August 1994 until July 1998, Mr. Sarnoff served as a litigation associate attorney at Wachtel Missry LLP (formerly known as Gold & Wachtel LLP). Since July 2018, Mr. Sarnoff has served as a member of the advisory committee of the New Jersey Association of School Resource Officers. From January 2015 until January 2018, Mr. Sarnoff served as board President of Fort Lee Board of Education and served as a board member from January 2013 through January 2019. In September of 2020, Mr. Sarnoff was appointed to a three year term on the Diversity, Equity & Inclusion Committee of the New York City Bar Association. Mr. Sarnoff received his Juris Doctor from Rutgers University School of Law and his bachelor of arts from Hofstra University. Mr. Sarnoff is admitted to the New York and New Jersey (retired status) state bars. We believe that Mr. Sarnoff is qualified to serve as a director because of his legal experience as well as his extensive experience in executive leadership and business development.

**Graig Springer**

Graig Springer has served as a director of the Company since February 2020. Since April 2021, Mr. Springer has served as Vice President for Brookfield Asset Management Inc. ("Brookfield") in their Legal and Regulatory Department ,and from August 2020 to April 2021, he served as a consultant to Brookfield. From May 2019 to August 2019, Mr. Springer assisted with product development and governance at Invesco U.S., an investment management company, and from December 2013 to May 2019, he served in various capacities at OppenheimerFunds, Inc., an investment management company acquired by Invesco U.S., including distribution compliance and product development. In addition, Mr. Springer served on the Sub-Adviser Oversight Committee at OppenheimerFunds, Inc. Mr. Springer received his bachelor of arts from Columbia University and his Juris Doctor from Fordham University School of Law. Mr. Springer also holds a Series 7 and a Series 24 license. We believe that Mr. Springer is qualified to serve as a director because of his fifteen years of experience within the financial services industry overseeing and advising firms' compliance with federal rules and regulations.

**Family Relationships**

There are no family relationships among any of our executive officers or directors.

**Arrangements between Officers and Directors**

Except as set forth herein, to our knowledge, there is no arrangement or understanding between any of our officers or directors and any other person pursuant to which the officer or director was selected to serve as an officer or director.

**Involvement in Certain Legal Proceedings**

We are not aware of any of our directors or officers being involved in any legal proceedings in the past ten years relating to any matters in bankruptcy, insolvency, criminal proceedings (other than traffic and other minor offenses), or being subject to any of the items set forth under Item 401(f) of Regulation S-K.

**Committees of Our Board of Directors**

Our board of directors directs the management of our business and affairs, as provided by Nevada law, and conducts its business through meetings of the board of directors and its standing committees. We have a standing audit committee, compensation committee and nominating and corporate governance committee. In addition, from time to time, special committees may be established under the direction of the board of directors when necessary to address specific issues.

Our board of directors has determined that all of the members of the audit committee, the compensation committee and the nominating and corporate governance committee are independent as defined under the applicable rules of The Nasdaq Capital Market, including, in the case of all of the members of our audit committee, the independence requirements contemplated by Rule 10A-3 under the Exchange Act. In making such determination, the board of directors considered the relationships that each director has with our Company and all other facts and circumstances that the board of directors deemed relevant in determining director independence, including the beneficial ownership of our capital stock by each director.

**Audit Committee**

Our audit committee will be responsible for, among other things:

- approving and retaining the independent registered public accounting firm to conduct the annual audit of our consolidated financial statements;
- reviewing the proposed scope and results of the audit;
- reviewing and pre-approval of audit and non-audit fees and services;
- reviewing accounting and financial controls with the independent registered public accounting firm and our financial and accounting staff;
- reviewing and approving transactions between us and our directors, officers and affiliates;
- establishing procedures for complaints received by us regarding accounting matters;
- overseeing internal audit functions, if any; and
- preparing the report of the audit committee that the rules of the Securities and Exchange Commission require to be included in our annual meeting proxy statement.

Our audit committee consists of Wayne Linsley, David Sarnoff and Graig Springer, with Wayne Linsley serving as chair. Each member of our audit committee meets the financial literacy requirements of the Nasdaq rules. In addition, our board of directors has determined that Wayne Linsley qualifies as an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K.

Our board of directors adopted a written charter for the audit committee which is available on our website at www.hoththerapeutics.com.

***Compensation Committee***

Our compensation committee is responsible for, among other things:

- reviewing and recommending the compensation arrangements for management, including the compensation for our president and chief executive officer;
- establishing and reviewing general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals;
- administering our stock incentive plans; and
- preparing the report of the compensation committee that the rules of the Securities and Exchange Commission require to be included in our annual meeting proxy statement.

As of December 31, 2021, our compensation committee consisted of Wayne Linsley, Vadim Mats and David Sarnoff, with Wayne Linsley serving as chair. Currently, our compensation committee consists of Wayne Linsley, Graig Springer and David Sarnoff, with Wayne Linsley serving as chair.

Our board of directors adopted a written charter for the compensation committee which is available on our website at www.hoththerapeutics.com.

***Nominating and Governance Committee***

Our nominating and governance committee is responsible for, among other things:

- identifying and nominating members of the board of directors;
- developing and recommending to the board of directors a set of corporate governance principles applicable to our Company; and
- overseeing the evaluation of our board of directors.

As of December 31, 2021, our nominating and corporate governance committee consisted of Vadim Mats, Graig Springer and David Sarnoff, with Vadim Mats serving as chair. Currently, our nominating and corporate governance committee consists of Wayne Linsley, Graig Springer and David Sarnoff, with Graig Springer serving as chair.

Our board of directors adopted a written charter for the nominating and corporate governance committee which is available on our website at www.hoththerapeutics.com.

**Scientific Advisory Board**

In July 2017, the board of directors formed a Scientific Advisory Board (formerly known as the Technology Advisory Board). The members of such board are as follows: (i)Dr. Mario Lacouture, Dr. William Weglicki, and Dr. Adam Friedman as Medical Doctor members and (ii) Dr. Andrew Herr, Dr. Michael Peters, Dr. Glenn Cruse, Dr. Vincent Njar, Dr. Carla Yuede, Dr. John Cirrito and Sergio Traversa as Non-Medical Doctor members.

**Delinquent Section 16(a) Reports**

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than 10% of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities.

To our knowledge, based solely upon a review of Forms 3, 4, and 5 filed with the SEC during the fiscal year ended December 31, 2021, we believe that, except as set forth below, our directors, executive officers, and greater than 10% beneficial owners have complied with all applicable filing requirements during the fiscal year ended December 31, 2021.

- AIkido Pharma Inc. failed to report 1 transaction on time on a Form 5.

**Code of Business Code and Ethics Conduct**

We adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code is posted on our website at www.hoththerapeutics.com. Disclosure regarding any amendments to, or waivers from, provisions of the code of conduct and ethics that apply to our directors, principal executive and financial officers will be posted on the "Investors-Corporate Governance" section of our website at www.hoththerapeutics.com or will be included in a Current Report on Form 8-K, which we will file within four business days following the date of the amendment or waiver.

**Changes in Nominating Procedures**

None.

**ITEM 11. EXECUTIVE COMPENSATION**

*Summary Compensation Table*

The following table sets forth the compensation paid or accrued during the fiscal year ended December 31, 2021 and 2020 to our principal executive officer and two additional officers (collectively, the "named executive officers"):

- Robb Knie, Chief Executive Officer
- Stefanie Johns, Chief Scientific Officer
- Jane H. Springer, Vice President of Operations

| Name and Principal Position | Year | Salary ($) | Bonus ($) | Stock Awards ($) | Option Awards ($) | Non-Equity Incentive Plan Compensation ($) | Nonqualified deferred compensation earnings ($) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|---|---|---|
| Robb Knie | 2021 | 400,000 | 200,000 | - | 388,919 | - | - | 86,261 (2) | 1,075,180 |
| Chief Executive Officer and President | 2020 | 350,000 | 175,000 | - | 195,186 | - | - | 61,002 (3) | 781,188 |
| Stefanie Johns (1) | 2021 | 253,333 | 10,000 | - | 216,066 | - | - | 46,894 (4) | 526,293 |
| Chief Scientific Officer | 2020 | 62,879 | - | - | - | - | - | 13,955 (5) | 76,834 |
| Jane H. Springer | 2021 | 191,875 | 85,000 | - | 259,279 | - | - | 47,438 (6) | 583,592 |
| Vice President of Operations | 2020 | 175,000 | 40,000 | - | 109,792 | - | - | 31,023 (7) | 355,815 |

(1) Stefanie Johns was appointed as Chief Scientific Officer of the Company effective as of September 8, 2020.

(2) This amount reflects employer contributions to the 401(k) Plan of $15,917 and executive health or supplemental medical insurance premiums of $70,344.

(3) This amount reflects employer contributions to executive health or supplemental medical insurance premiums of $61,002.

(4) This amount reflects employer contributions to the 401(k) Plan of $6,475 and executive health or supplemental medical insurance premiums of $40,419.

(5) This amount reflects employer contributions to executive health or supplemental medical insurance premiums of $13,955.

(6) This amount reflects employer contributions to the 401(k) Plan of $8,546 and executive health or supplemental medical insurance premiums of $38,892.

(7) This amount reflects employer contributions to executive health or supplemental medical insurance premiums of $31,023.

**Outstanding Equity Awards at December 31, 2021**

The following table provides information regarding option awards held by each of our named executive officers that were outstanding as of December 31, 2021. There were no stock awards or other equity awards outstanding as of December 31, 2021.

| | Option Awards | | | |
|---|---|---|---|---|
| Name | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable | Option Exercise Price ($) | Option Expiration Date |
| Robb Knie | 250,000(1) | - | $ 5.26 | 12/24/2029 |
| | 80,000(2) | - | $ 3.05 | 7/21/2030 |
| | 225,000(3) | - | $ 2.11 | 1/29/2031 |
| Stefanie Johns | 125,000(4) | - | $ 2.11 | 1/29/2031 |
| Jane H. Springer | 50,000(5) | - | $ 5.26 | 12/24/2029 |
| | 45,000(6) | - | $ 3.05 | 7/21/2030 |
| | 150,000(7) | - | $ 2.11 | 1/29/2031 |

(1) Stock options granted to Robb Knie vested in full immediately upon grant.

(2) Stock options granted to Robb Knie vested in full immediately upon grant.

(3) Stock options granted to Robb Knie vested in full immediately upon grant.

(4) Stock options granted to Stefanie Johns vested in full immediately upon grant.

(5) Stock options granted to Jane Springer vested in full immediately upon grant.

(6) Stock options granted to Jane Springer vested in full immediately upon grant.

(7) Stock options granted to Jane Springer vested in full immediately upon grant.

**Non-Employee Director Compensation**

The following table presents the total compensation for each person who served as a non-employee member of our board of directors and received compensation for such service during the fiscal year ended December 31, 2021. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2021.

| Name | Fees earned or paid in cash ($) | Stock Awards ($) | Option Awards ($) | Non-Equity Incentive Plan Compensation ($) | Nonqualified deferred compensation earnings ($) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|---|
| Vadim Mats (1) | 30,000 | - | 57,041 | - | - | - | 87,041 |
| David Sarnoff | 30,000 | - | 57,041 | - | - | - | 87,041 |
| Graig Springer | 30,000 | - | 57,041 | - | - | - | 87,041 |
| Wayne Linsley | 30,000 | - | 57,041 | - | - | - | 87,041 |

(1) Vadim Mats resigned from the Company's board of directors effective as of January 31, 2022.

**Non-Employee Director Compensation Policy**

Our directors receive $30,000 cash compensation per year for their service on the board of directors, as well as reimbursement for out-of-pocket expenses with respect to such directors' attendance at meetings of the board of directors of the Company.

Committee chairs receive an additional one-time $6,000 cash compensation upon appointment for their added services in such roles.

In addition, in January 2021, non-employee directors received options to purchase up to 33,000 shares of the Company's common stock at an exercise price of $2.11 per share.

**Employment Agreements**

*Robb Knie Employment Agreement*

On February 20, 2019 (the "Knie Effective Date"), the Company entered into an amended and restated employment agreement with Robb Knie, as amended on June 25, 2021 (as amended, the "Employment Agreement"), pursuant to which Robb Knie serves as Chief Executive Officer of the Company. The term of the Employment Agreement will continue for a period of one year from the Knie Effective Date and automatically renews for successive one year periods at the end of each term until either party delivers written notice of their intent not to review at least six months prior to the expiration of the then effective term. Pursuant to the Employment Agreement, Mr. Knie (i) shall receive an annual base salary of $450,000 (effective as of July 1, 2021) and (ii) shall be entitled to receive an annual bonus of $350,000 (effective as July 1, 2021), which annual bonus may be increased by the compensation committee of the Company in its sole discretion, upon the achievement of additional criteria established by the compensation committee from time to time. In addition, Mr. Knie is also entitled to participate in any and all Benefit Plans (as defined in the Employment Agreement), from time to time, in effect for senior executives, along with vacation, sick and holiday pay in accordance with the Company's policies established and in effect from time to time.

The Employment Agreement may be terminated upon (i) Mr. Knie's death, (ii) Mr. Knie's Total Disability (as defined in the Employment Agreement), (iii) expiration of the term if either party has provided a timely non-renewal notice, (iv) at Mr. Knie's option (A) upon 90 days prior written notice; provided, however, Mr. Knie may terminate the Employment Agreement by providing written notice at any time within 40 days of the consummation of a Change in Control Transaction (as defined in the Employment Agreement) or (B) for Good Reason (as defined in the Employment Agreement); or (v) at the Company's option (A) for Cause (as defined in the Employment Agreement) or (B) upon 90 days prior written notice without Cause (as defined in the Employment Agreement).

Upon the termination of Mr. Knie's employment for any reason, whether by Mr. Knie or by the Company, Mr. Knie shall be paid (i) accrued but unpaid compensation and vacation pay through the date of termination, (ii) any other benefits accrued to him under any Benefit Plans outstanding at the date of termination and (iii) the reimbursement of expenses incurred on or prior to such date (collectively, the "Severance Package"). In addition to the Severance Package, upon Mr. Knie's termination for death or Total Disability, Mr. Knie or his estate or beneficiaries, as applicable, shall receive (i) 24 months base salary at the then current rate, (ii) if Mr. Knie elects continuation coverage for group health coverage pursuant to COBRA Rights (as defined in the Employment Agreement), then for a period of 24 months following Mr. Knie's termination he will be obligated to pay only the portion of the full COBRA Rights cost of the coverage equal to an active employee's share of premiums (if any) for coverage for the respective plan year and (iii) payment on a pro-rated basis of any annual bonus or other payments earned in connection with any bonus plan to which the Mr. Knie was a participant as of the date of death or Total Disability. Upon Mr. Knie's termination for Good Reason, without Cause or Mr. Knie's termination upon 90 days prior written notice to the Company or notice to the Company within 40 days of the consummation of a Change in Control Transaction, in addition to the Severance Package, Mr. Knie shall receive (i) 24 months base salary at the then current rate, (ii) if Mr. Knie elects continuation coverage for group health coverage pursuant to COBRA Rights, then for a period of 24 months following Mr. Knie's termination he will be obligated to pay only the portion of the full COBRA Rights cost of the coverage equal to an active employee's share of premiums (if any) for coverage for the respective plan year, (iii) payment on a pro-rated basis of any annual bonus or other payments earned in connection with any bonus plan to which the Mr. Knie was a participant as of the date of termination; provided, however, that the pro-rated annual bonus payable pursuant to the Employment Agreement shall be no less than $200,000 and (iv) any equity grants to Mr. Knie shall immediately vest upon termination of Mr. Knie's employment by him for Good Reason or by the Company at its option upon 90 days prior written notice to Mr. Knie, without Cause. The Employment Agreement also contains covenants prohibiting Mr. Knie from disclosing confidential information with respect to the Company.

*Jane Springer Employment Agreement*

On November 13, 2019 (the "Springer Effective Date"), the Company entered into an Amended and Restated Employment Agreement with Jane Springer, as amended on June 25, 2021 (as amended, the "Springer Employment Agreement"), pursuant to which Mrs. Springer serves as Vice President of Operations of the Company. The term of the Springer Employment Agreement will continue for a period of one year from the Springer Effective Date and automatically renews for successive one year periods at the end of each term until either party delivers written notice of their intent not to review at least 30 days prior to the expiration of the then effective term. Pursuant to the terms of the Springer Employment Agreement, Mrs. Springer (i) shall receive an annual base salary of $200,000 (effective as of July 1, 2021), (ii) shall be entitled to earn a bonus, subject to the sole discretion of the Company's Board and (iii) shall be eligible to receive awards pursuant to the Company's equity incentive plans, subject to the sole discretion of the Company's compensation committee. Mrs. Springer is also entitled to participate in any and all Employee Benefit Plans (as defined in the Springer Employment Agreement), from time to time, that are then in effect along with vacation, sick and holiday pay in accordance with the Company's policies established and in effect from time to time.

The Springer Employment Agreement may be terminated by either the Company or Mrs. Springer at any time and for any reason upon 10 days prior written notice. Upon termination of the Springer Employment Agreement, Mrs. Springer shall be entitled to (i) any equity award that has vested prior to the termination date, (ii) reimbursement of expenses incurred on or prior to such termination date and (iii) such employee benefits to which Mrs. Springer may be entitled as of the termination date (collectively, the "Accrued Amounts"). The Springer Employment Agreement shall also terminate upon Mrs. Springer's death or the Company may terminate Mrs. Springer's employment upon her Disability (as defined in the Springer Employment Agreement). Upon the termination of Mrs. Springer's employment for death or Disability, Mrs. Springer shall be entitled to receive the Accrued Amounts. The Springer Employment Agreement also contains covenants prohibiting Mrs. Springer from disclosing confidential information with respect to the Company.

*Stephanie Johns Employment Agreement*

On August 28, 2020, the Company entered into an employment agreement with Dr. Johns, as amended on January 29, 2021 and June 25, 2021 (as amended, the "Johns Employment Agreement"), pursuant to which Dr. Johns serves as Chief Scientific Officer of the Company effective as of September 8, 2020 (the "Effective Date"). The term of the Johns Employment Agreement will continue for a period of one year from the Effective Date and automatically renews for successive one year periods at the end of each term until either party delivers written notice of their intent not to review at least 60 days prior to the expiration of the then effective term. Pursuant to the terms of the Johns Employment Agreement, Dr. Johns (i) shall receive an annual base salary of $265,000 (effective as of July 1, 2021), (ii) shall be eligible to receive an annual bonus as determined by the Company's compensation committee and (iii) shall be eligible to receive grants of awards under the Company's equity incentive plans as determined by the Company's compensation committee. Furthermore, Dr. Johns shall be eligible to participate in Benefit Plans (as defined in the Johns Employment Agreement) from time to time, in effect for senior employees.

The Johns Employment Agreement may be terminated upon (i) Dr. Johns' death, (ii) Dr. Johns' Total Disability (as defined in the Johns Employment Agreement), (iii) expiration of the term if either party has provided a timely non-renewal notice, (iv) at Dr. Johns' option (A) upon 60 days prior written notice or (B) for Good Reason (as defined in the Johns Employment Agreement) or (v) at the Company's option for Cause (as defined in the Johns Employment Agreement). In the event Dr. Johns' employment is terminated for death or Total Disability, Dr. Johns shall receive (i) her accrued but unpaid compensation and vacation through the date of death or Total Disability, (ii) the reimbursement unpaid of expenses, (iii) Benefit Plans for a period of 12 months following her death and (iv) payment, on a pro-rated basis, of any bonus or other payments earned by Dr. Johns as of the date of her death or Total Disability. In the event Dr. Johns' employment is terminated upon the expiration of the term of the Johns Employment Agreement where the Company has offered to renew the term but Dr. Johns has declined such renewal, Dr. Johns shall receive (i) her accrued but unpaid compensation and vacation through the date of termination, (ii) any other benefits accrued to her under any Benefit Plans and (iii) the reimbursement of unpaid expenses. In the event Dr. Johns' employment is terminated upon the expiration of the term of the Johns Employment Agreement as a result of the Company tendering a non-renewal notice (other than for Cause), Dr. Johns shall receive the same payment she would receive if she terminated her employment for Good Reason. In the event Dr. Johns' employment is terminated for Good Reason, Dr. Johns shall receive (i) her accrued but unpaid compensation and vacation through the date of termination, (ii) any other benefits accrued to her under any Benefit Plans, (iii) the reimbursement of unpaid expenses, (iv) a cash payment of 12 months of her then base salary, (v) Benefit Plans for a period of 12 months following the date of termination and (vi) payment on a pro-rated basis of any bonus or other payments earned in connection with any bonus plan to which she was a participant as of the date of termination. Any options or restricted stock owned by Dr. Johns shall immediately vest upon her termination for Good Reason or termination by the Company without Cause. In the event Dr. Johns' employment is terminated by her upon 60 days prior notice or by the Company for Cause, Dr. Johns shall receive (i) her accrued but unpaid compensation and vacation through the date of termination, (ii) continued provision for a period of one month after the date of termination of benefits under the Benefit Plans and (iii) the reimbursement of unpaid expenses. The Johns Employment Agreement also contains covenants prohibiting Mrs. Springer from disclosing confidential information with respect to the Company.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The following table sets forth certain information regarding beneficial ownership of shares of our common stock as of March 28, 2022 by (i) each person known to beneficially own more than 5% of our outstanding common stock, (ii) each of our directors, (iii) each of our named executive officers and (iv) all of our directors and named executive officers as a group. Except as otherwise indicated, the persons named in the table below have sole voting and investment power with respect to all shares beneficially owned, subject to community property laws, where applicable.

| Beneficial Owner[1] | Shares of Common Stock Beneficially Owned | Percentage [2] |
|---|---|---|
| **Directors and Named Executive Officers:** | | |
| Robb Knie | 1,863,259(3) | 7.44% |
| Stefanie Johns | 375,000(4) | * |
| Wayne Linsley | 90,392(5) | * |
| David Sarnoff | 148,000(6) | * |
| Jane H. Springer | 613,209(7) | 2.50% |
| Graig Springer | 613,209(8) | 2.50% |
| All Named Executive Officers and Directors as a Group (6 persons) | 3,089,860 | 11.79% |
| **5% or Greater Shareholders:** | | |
| Intracoastal Capital LLC (9)<br>245 Palm Trail<br>Delray Beach, FL 33483 | 1,425,200(10) | 5.61% |

* Represents beneficial ownership of less than 1%.

(1) The address of each person is c/o Hoth Therapeutics, Inc., 1 Rockefeller Plaza, Suite 1039, New York, New York 10020 unless otherwise indicated herein.

(2) The calculation in this column is based upon 23,975,098 shares of common stock outstanding on March 28, 2022. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to the subject securities. Shares of common stock that are currently exercisable or convertible within 60 days of March 28, 2022 are deemed to be beneficially owned by the person holding such securities for the purpose of computing the percentage beneficial ownership of such person, but are not treated as outstanding for the purpose of computing the percentage beneficial ownership of any other person.

(3) Includes options to purchase up to 1,055,000 shares of the Company's common stock.

(4) Includes options to purchase up to 375,000 shares of the Company's common stock.

(5) Includes options to purchase up to 88,000 shares of the Company's common stock. Excludes 941 shares of common stock which are subject to vesting.

(6) Includes options to purchase up to 123,000 shares of the Company's common stock.

(7) Includes (i) 27,817 shares of the Company's common stock held by Jane H. Springer, (ii) options to purchase up to 495,000 shares of the Company's common stock held by Jane H. Springer, (iii) options to purchase up to 88,000 shares of the Company's common stock held by Graig Springer and (iv) 2,392 shares of the Company's common stock held by Graig Springer. Excludes 941 shares of the Company's common stock held by Graig Springer which are subject to vesting. Graig Springer is the spouse of Jane H. Springer.

(8) Includes (i) 2,392 shares of the Company's common stock held by Graig Springer, (ii) options to purchase up to 88,000 shares of the Company's common stock held by Graig Springer, (iii) 27,817 shares of the Company's common stock held by Jane H. Springer and (iv) options to purchase up to 495,000 shares of the Company's common stock held by Jane H. Springer. Excludes 941 shares of the Company's common stock held by Graig Springer which are subject to vesting. Jane H. Springer is the spouse of Graig Springer.

(9) Mitchell P. Kopin ("Mr. Kopin") and Daniel B. Asher ("Mr. Asher"), each of whom are managers of Intracoastal Capital LLC ("Intracoastal"), have shared voting control and investment discretion over the securities reported herein that are held by Intracoastal. As a result, each of Mr. Kopin and Mr. Asher may be deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange Act) of the securities reported herein that are held by Intracoastal.

(10) Pursuant to the Schedule 13G filed by Intracoastal Capital LLC on February 11, 2022, includes warrants to purchase up to 1,425,200 shares of common stock. The warrants contain an ownership limitation such that the holder may not exercise such warrants to the extent that such exercise would result in the holder's beneficial ownership being in excess of 9.99% of the Company's issued and outstanding common stock together with all shares owned by the holder and its affiliates.

**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table summarizes information about our equity compensation plans as of December 31, 2021.

| Plan Category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (a) | Weighted average exercise price of outstanding options, warrants and rights | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) |
|---|---|---|---|
| Equity compensation plans approved by security holder | 1,321,212 | $ 3.37 | 2,083,061 |
| Equity compensation plans not approved by security holder | - | - | - |
| Total | 1,321,212 | | 2,083,061 |

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The following includes a summary of transactions during our fiscal years ended December 31, 2021 and December 31, 2020 to which we have been a party, including transactions in which the amount involved in the transaction exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described elsewhere in this Annual Report on Form 10-K. We are not otherwise a party to a current related party transaction, and no transaction is currently proposed, in which the amount of the transaction exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years and in which a related person had or will have a direct or indirect material interest.

**Laidlaw & Company (UK) Ltd. ("Laidlaw")**

On March 26, 2020, we entered into an underwriting agreement with Laidlaw pursuant to which we paid Laidlaw a fee in the amount of 9% of the gross proceeds of our sale of 1,449,275 shares of common stock, or approximately $400,000. We also reimbursed Laidlaw approximately $50,000 for management fee and certain out-of-pocket expenses, including the fees and disbursements of their counsel in an amount equal to $25,000. In addition, Laidlaw received a warrant to purchase 72,464 shares of our common stock at an exercise price of $4.14 per share.

**Related Person Transaction Policy**

We have adopted a formal policy regarding approval of transactions with related parties. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds the lesser of $120,000 or 1% of our total assets at the end of our last completed fiscal year. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our code of business conduct and ethics, our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our shareholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

**Director Independence**

Our board of directors determined that a majority of the board during the year ended December 31, 2021 consisted of members who were "independent" as that term is defined under Nasdaq Listing Rule 5605(a)(2). The Board considered Wayne Linsley, Vadim Mats, David Sarnoff and Graig Springer to be "independent."

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The following table sets forth the aggregate fees billed by WithumSmith+Brown, PC as described below:

| | 2021 | 2020 |
|---|---|---|
| Audit Fees | $ 98,365 | $ 91,567 |
| Audit Related Fees | - | - |
| Tax Fees | 3,605 | - |
| All Other Fees | - | - |
| Total | $ 101,970 | $ 91,567 |

**Audit Fees:** Audit fees consist of fees billed for professional services performed by WithumSmith+Brown, PC for the audit of our annual consolidated financial statements, the review of interim consolidated financial statements, and related services that are normally provided in connection with registration statements. There were $98,365 and $91,567 of such fees incurred by the Company in the fiscal years ended December 31, 2021 and 2020, respectively.

**Audit-Related Fees:** Audit related fees may consist of fees billed by an independent registered public accounting firm for assurance and related services that are reasonably related to the performance of the audit or review of our consolidated financial statements. There were no such fees incurred by the Company in the fiscal years ended December 31, 2021 and 2020.

**Tax Fees:** Tax fees may consist of fees for professional services, including tax compliance performed by WithumSmith+Brown, PC. There were $3,605 and $0 of such fees incurred by the Company in the fiscal years ended December 31, 2021 and 2020, respectively.

**All Other Fees:** There were no such fees incurred by the Company in the fiscal years ended December 31, 2021 and 2020.

**Pre-Approval Policies and Procedures**

In accordance with Sarbanes-Oxley, our audit committee charter requires the audit committee to pre-approve all audit and permitted non-audit services provided by our independent registered public accounting firm, including the review and approval in advance of our independent registered public accounting firm's annual engagement letter and the proposed fees contained therein. The audit committee has the ability to delegate the authority to pre-approve non-audit services to one or more designated members of the audit committee. If such authority is delegated, such delegated members of the audit committee must report to the full audit committee at the next audit committee meeting all items pre-approved by such delegated members. In the fiscal years ended December 31, 2021 and 2020 all of the services performed by our independent registered public accounting firm were pre-approved by the audit committee.

## PART IV

### ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

**(a) The following documents are filed as part of this report:**

(1) Financial Statements:



The consolidated financial statements required by this Item are included beginning at page F-1.

(1) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the consolidated financial statements or the notes thereto.

**(b) Exhibits**

**EXHIBIT INDEX**

| Exhibit Number | Exhibit |
|---|---|
| 3.1 | Articles of Incorporation (Incorporated by reference to Exhibit 3.1 to the Company's Form S-1/A filed on December 14, 2018) |
| 3.2 | Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.2 to the Company's Form S-1/A filed on December 14, 2018) |
| 3.3 | Certificate of Designations, Preferences and Rights of the Series A Convertible Preferred Stock (Incorporated by reference to Exhibit 3.3 to the Company's Form S-1/A filed on December 14, 2018) |
| 3.4 | Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed on February 20, 2019) |
| 3.5 | Amended and Restated Bylaws (Incorporated by reference to Exhibit 3.2 to the Company's Form 8-K filed on February 20, 2019) |
| 4.1 | Specimen Stock Certificate evidencing the shares of common stock (Incorporated by reference to Exhibit 4.1 to the Company's Form S-1/A filed on December 14, 2018) |
| 4.2 | Form of Underwriter Warrant (Incorporated by reference to Exhibit 4.2 to the Company's Form S-1/A filed on January 11, 2019) |
| 4.3 | Form of Warrant (Incorporated by reference to Exhibit 4.1 to the Company's Form 8-K filed on March 25, 2020) |
| 4.4 | Form of Warrant (Incorporated by reference to Exhibit 4.1 to the Company's Form 8-K filed on May 22, 2020) |
| 4.5* | Description of the Registrant's Securities |
| 10.1+ | Amended and Restated Employment Agreement between Hoth Therapeutics, Inc. and Robb Knie (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on February 20, 2019) |
| 10.2 | Office Service Agreement with Regus dated June 26, 2017 (Incorporated by reference to Exhibit 10.7 to the Company's Form S-1/A filed on December 14, 2018) |
| 10.3 | Form of Warrant (Incorporated by reference to Exhibit 10.8 to the Company's Form S-1/A filed on December 14, 2018) |
| 10.4 | Form of Investor Rights Agreement (Incorporated by reference to Exhibit 10.10 to the Company's Form S-1/A filed on December 14, 2018) |
| 10.5+ | 2018 Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Company's Form S-8 filed on February 4, 2022) |
| 10.6 | Renewal Agreement with Regus dated April 14, 2020 (Incorporated by reference to Exhibit 10.9 to the Company's Form 10-K filed on March 2, 2020 ) |
| 10.7 | Form of Registration Rights Agreement (Incorporated by reference to Exhibit 10.14 to the Company's Form S-1/A filed on December 14, 2018) |
| 10.8+ | Employment Agreement between Hoth Therapeutics, Inc. and David Briones (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on March 7, 2019) |

| | |
|---|---|
| 10.9 | Form of Warrant (Incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed on August 21, 2019) |
| 10.10 | Form of Registration Rights Agreement (Incorporated by reference to Exhibit 10.4 to the Company's Form 8-K filed on August 21, 2019) |
| 10.11 | Form of Placement Agent Warrant (Incorporated by reference to Exhibit 10.5 to the Company's Form 8-K filed on August 21, 2019) |
| 10.12+ | Amended and Restated Employment Agreement between Hoth Therapeutics, Inc. and Jane H. Springer (Incorporated by reference to Exhibit 10.7 to the Company's Form 10-Q filed on November 12, 2019) |
| 10.13 | License Agreement with North Carolina State University dated November 20, 2019 (Incorporated by reference to Exhibit 10.22 to the Company's Form 10-K filed on March 2, 2020) |
| 10.14 | Development and Royalty Agreement by and between the Company and Voltron Therapeutics, Inc. dated March 23, 2020 (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on March 23, 2020) |
| 10.15## | Exclusive License Agreement between the Company and Virginia Commonwealth University Intellectual Property Foundation dated May 18, 2020 (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on May 19, 2020) |
| 10.16## | Sponsored Project Agreement by and between the Company and Virginia Commonwealth University (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on July 2, 2020) |
| 10.17## | Sublicense Agreement by and between the Company and Isoprene Pharmaceutics, Inc. dated July 30, 2020 (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on August 5, 2020) |
| 10.18 | License Agreement by and between the University of Cincinnati and Chelexa BioSciences, Inc. dated February 27, 2013 assigned to the Company on May 14, 2020 (Incorporated by reference to Exhibit 10.3 to the Company's Form 10-Q filed on August 13, 2020) |
| 10.19 | First Amendment to Exclusive License Agreement by and between the University of Cincinnati and Chelexa BioSciences, Inc. dated April 17, 2013 assigned to the Company on May 14, 2020 (Incorporated by reference to Exhibit 10.4 to the Company's Form 10-Q filed on August 13, 2020) |
| 10.20 | Second Amendment to Exclusive License Agreement by and between the University of Cincinnati and Chelexa BioSciences, Inc. dated February 27, 2013 assigned to the Company on May 14, 2020 (Incorporated by reference to Exhibit 10.5 to the Company's Form 10-Q filed on August 13, 2020) |
| 10.21 | Assignment and Assumption Agreement by and between the Company and Chelexa BioSciences, Inc. dated May 14, 2020 (Incorporated by reference to Exhibit 10.6 to the Company's Form 10-Q filed on August 13, 2020) |
| 10.22 | Royalty Agreement by and between the Company and Chelexa BioSciences, Inc. dated May 14, 2020 (Incorporated by reference to Exhibit 10.7 to the Company's Form 10-Q filed on August 13, 2020) |
| 10.23 | Novation Agreement by and among the Company, Chelexa BioSciences, Inc. and the University of Cincinnati dated May 14, 2020 (Incorporated by reference to Exhibit 10.8 to the Company's Form 10-Q filed on August 13, 2020) |
| 10.24 | Patent License Agreement by and between the Company and the George Washington University dated August 7, 2020 (Incorporated by reference to Exhibit 10.9 to the Company's Form 10-Q filed on August 13, 2020) |
| 10.25+ | Employment Agreement by and between the Company and Stefanie Johns dated August 28, 2020 (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on August 31, 2020) |
| 10.26## | Sponsored Research Agreement by and between the Company and the George Washington University (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on September 21, 2020) |
| 10.27 | Form of Warrant (Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed on January 8, 2021) |
| 10.28 | Form of Registration Rights Agreement (Incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed on January 8, 2021) |
| 10.29 | Form of Placement Agent Warrant (Incorporated by reference to Exhibit 10.4 to the Company's Form 8-K filed on January 8, 2021) |

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|---|---|
| 10.30+ | First Amendment to the Employment Agreement between Hoth Therapeutics, Inc. and Stefanie Johns (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on January 29, 2021) |
| 10.31 | Form of Common Stock Warrants (Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed on March 9, 2021) |
| 10.32 | Form of Pre-Funded Warrants (Incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed on March 9, 2021) |
| 10.33 | Form of Registration Rights Agreement (Incorporated by reference to Exhibit 10.4 to the Company's Form 8-K filed on March 9, 2021) |
| 10.34 | Form of Placement Agent Warrants (Incorporated by reference to Exhibit 10.5 to the Company's Form 8-K filed on March 9, 2021) |
| 10.35+ | First Amendment to the Amended and Restated Employment Agreement between the Company and Robb Knie dated June 25, 2021 (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on June 30, 2021) |
| 10.36+ | Second Amendment to the Employment Agreement between the Company and Stefanie Johns dated June 25, 2021 (Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed on June 30, 2021) |
| 10.37+ | First Amendment to the Amended and Restated Employment Agreement between the Company and Jane Springer dated June 25, 2021 (Incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed on June 30, 2021) |
| 21.1* | Subsidiaries of the registrant |
| 23.1* | Consent of WithumSmith+Brown, PC |
| 31.1* | Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2* | Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32.1* | Certification of the Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 101.INS* | Inline XBRL Instance Document |
| 101.SCH* | Inline XBRL Taxonomy Extension Schema Document |
| 101.CAL* | Inline XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF* | Inline XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB* | Inline XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE* | Inline XBRL Taxonomy Extension Presentation Linkbase Document |
| 104* | Cover Page Interactive Data File – the cover page of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2021 is formatted in Inline XBRL |

* Filed herewith.
\+ Indicates a management contract or any compensatory plan, contract or arrangement.
\# Confidential treatment has been requested to a portion of this exhibit, and such confidential portion has been deleted and filed separately with the SEC.
\## Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

**ITEM 16. FORM 10-K SUMMARY**

Not applicable.

**SIGNATURES**

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized on this 29th day of March, 2022.

**HOTH THERAPEUTICS, INC.**

/s/ Robb Knie
Robb Knie
Chief Executive Officer
(Principal Executive Officer)

/s/ David Briones
David Briones
Chief Financial Officer
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ Robb Knie<br>Robb Knie | Chief Executive Officer, President and Director<br>(Principal Executive Officer) | March 29, 2022 |
| /s/ Stefanie Johns<br>Stefanie Johns | Chief Scientific Officer | March 29, 2022 |
| /s/ David Briones<br>David Briones | Chief Financial Officer<br>(Principal Financial and Accounting Officer) | March 29, 2022 |
| /s/ Wayne Linsley<br>Wayne Linsley | Director | March 29, 2022 |
| /s/ David B. Sarnoff<br>David B. Sarnoff | Director | March 29, 2022 |
| /s/ Graig Springer<br>Graig Springer | Director | March 29, 2022 |

# DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2021, Hoth Therapeutics, Inc. ("the Company") had one class of security registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), its common stock, par value $0.0001 per share (the "Common Stock").

## Description of Common Stock

The following description of the Company's Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to the Company's Articles of Incorporation, as amended (the "Articles of Incorporation"), and the Company's Amended and Restated Bylaws (the "Bylaws"), each of which is incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.5 is a part. The Company encourages you to read its Articles of Incorporation, Bylaws, and the applicable provisions of the Nevada Revised Statutes for additional information.

*Authorized Capital Shares*

The Company's authorized capital shares consist of 75,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share ("Preferred Stock"), of which 5,000,000 shares of Preferred Stock have been designated as Series A Convertible Preferred Stock, $0.0001 par value per share. As of December 31, 2021, there were 23,974,546 shares of Common Stock issued and outstanding and no shares of Preferred Stock issued and outstanding.

*Voting Rights*

Holders of the Company's Common Stock are entitled to one vote per share on all matters voted on by the Company's shareholders, including the election of directors. The Company's Articles of Incorporation and Bylaws do not provide for cumulative voting in the election of directors.

*Dividend Rights*

Holders of the Company's Common Stock are entitled, subject to the rights, privileges, restrictions and conditions attaching to any other class of shares ranking in priority to the Common Stock, to receive any dividend declared by the Company's board of directors.

*Liquidation Rights*

If the Company is voluntarily or involuntarily liquidated, dissolved or wound-up, the holders of Common Stock will be entitled to receive, after distribution in full of the preferential amounts, if any, all of the remaining assets available for distribution ratably in proportion to the number of shares of Common Stock held by them.

## Applicable Anti-Takeover Law

Set forth below is a summary of the provisions of the Company's Articles of Incorporation and Bylaws that could have the effect of delaying or preventing a change in control of the Company. The following description is only a summary, and it is qualified by reference to the Articles of Incorporation, Bylaws and relevant provisions of the Nevada Revised Statutes.

*Board of Directors Vacancies*

The Company's Bylaws authorize only its board of directors to fill vacant directorships. In addition, the number of directors constituting the Company's board of directors may be set only by resolution of the majority of the incumbent directors.

*Special Meeting of Shareholders*

The Company's Bylaws provide that special meetings of its shareholders may be called by the president of the Company, the board of directors or a committee of the board of directors that has been duly designated by the board of directors and whose powers and authority include the power to call such meetings.

*Advance Notice Requirements for Shareholder Proposals and Director Nominations*

The Company's Bylaws provide that shareholders seeking to bring business before its annual meeting of shareholders, or to nominate candidates for election as directors at its annual meeting of shareholders, must provide timely notice of their intent in writing. To be timely, a shareholder's notice must be delivered to the secretary at the Company's principal executive offices not later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event the date of the annual meeting is not within 25 days before or after such anniversary date, notice by the shareholder to be timely must be so delivered not later than the close of business on the 10th day following the day on which such notice of the date of annual meeting was mailed or public disclosure of the date of the annual meeting was made, whichever occurs first. These provisions may preclude the Company's shareholders from bringing matters before its annual meeting of shareholders or from making nominations for directors at its annual meeting of shareholders.

*Authorized but Unissued Share*

The Company's authorized but unissued shares of Common Stock and Preferred Stock are available for future issuance without shareholder approval and may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved Common Stock and Preferred Stock could render more difficult or discourage an attempt to obtain control of the Company by means of a proxy contest, tender offer, merger or otherwise.

**Exclusive Forum**

The Company's Bylaws provide that unless the Company consents in writing to the selection of an alternative forum, the Eighth Judicial District Court of Clark County, Nevada shall be the sole and exclusive forum for state law claims with respect to: (i) any derivative action or proceeding brought in the name or right of the Company or on its behalf, (ii) any action asserting a claim for breach of any fiduciary duty owed by any director, officer, employee or agent of the Company to the Company or the Company's shareholders, (iii) any action arising or asserting a claim arising pursuant to any provision of Nevada Revised Statutes Chapters 78 or 92A or any provision of the Company's Articles of Incorporation or Bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine, including, without limitation, any action to interpret, apply, enforce or determine the validity of the Company's Articles of Incorporation or Bylaws. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. The enforceability of similar exclusive forum provisions in other corporations' bylaws has been challenged in legal proceedings, and it is possible that a court could rule that this provision in the Company's Bylaws is inapplicable or unenforceable.

**Transfer Agent and Registrar**

The Company's transfer agent and registrar is Continental Stock Transfer & Trust Company whose address is 1 State Street, 30th Floor, New York , NY 10004.

**Listing**

The Company's Common Stock is listed on The Nasdaq Capital Market under the symbol "HOTH."

**Exhibit 21.1**

**List of Subsidiaries of Hoth Therapeutics, Inc.**

| Name | State/Country of Organization or Incorporation |
|---|---|
| Hoth Therapeutics Australia Pty Ltd | Australia |

**Exhibit 23.1**

**Consent of Independent Registered Public Accounting Firm**

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 No. 333-233563, Form S-3 No. 333-236887, Form S-3 No. 333-251994, Form S-3 No. 333-254638 and Form S-8 No. 333-262530 of Hoth Therapeutics, Inc. of our report dated March 29, 2022, relating to the consolidated financial statements, which appear in this Form 10-K.

/s/ WithumSmith+Brown, PC

New York, New York
March 29, 2022

**Exhibit 31.1**

**Certification of Chief Executive Officer of Hoth Therapeutics, Inc.**
**Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Robb Knie, certify that:

1. I have reviewed this Annual Report on Form 10-K of Hoth Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures, and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2022

/s/ Robb Knie
Robb Knie
Chief Executive Officer and President
(Principal Executive Officer)

**Exhibit 31.2**

**Certification of Chief Financial Officer of Hoth Therapeutics, Inc.**
**Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, David Briones, certify that:

1. I have reviewed this Annual Report on Form 10-K of Hoth Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures, and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2022

/s/ David Briones
David Briones
Chief Financial Officer
(Principal Financial and Accounting Officer)

**Exhibit 32.1**

**Statement of Chief Executive Officer and Chief Financial Officer**
**Pursuant to Section 1350 of Title 18 of the United States Code**

Pursuant to Section 1350 of Title 18 of the United States Code as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned, Robb Knie and David Briones, the Chief Executive Officer and Chief Financial Officer, respectively, of Hoth Therapeutics, Inc. (the "Company"), hereby certify that based on the undersigned's knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 29, 2022

/s/ Robb Knie
Robb Knie
Chief Executive Officer and President
(Principal Executive Officer)

Date: March 29, 2022

/s/ David Briones
David Briones
Chief Financial Officer
(Principal Financial and Accounting Officer)